

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN
DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION: MDL NO. 2187

THIS DOCUMENT RELATES TO ALL
CASES IN MDL NO. 2187 AND
SPECIFICALLY TO:

PAMELA DOUGLAS-JONES AND TOMMY JONES, Plaintiffs,
vs. Civil Action File No. 2:13:cv:17990
C.R. BARD, INC., Defendant.

KRISTIA GROOVER AND EARL GROOVER, Plaintiffs
vs. Civil Action File No. 2:12:cv:00173
C.R. BARD, INC., Defendant.

PAMELA RAE GRUMAN AND LARRY FRANK GRUMAN, Plaintiffs
vs. Civil Action File No. 2:13:cv:02168
C.R. BARD, INC., Defendant.

ALMA D. MESSER, Plaintiffs
vs. Civil Action File No. 2:12:cv:06600
C.R. BARD, INC., Defendant.

DEBRA A. MITCHELL AND JERRY MITCHELL, Plaintiffs
vs. Civil Action File No. 2:12:cv:05532
C.R. BARD, INC., Defendant.

DEBORAH VILLNAVE, Plaintiffs
vs. Civil Action File No. 2:11:cv:00837
C.R. BARD, INC., Defendant.

MYRA WHITE, Plaintiffs
vs. Civil Action File No. 2:13:cv:02038
C.R. BARD, INC., Defendant.

ORAL AND VIDEOTAPED DEPOSITION OF
KEITH O. REEVES, M.D.
NOVEMBER 3RD, 2014
VOLUME 1

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 ORAL AND VIDEOTAPED DEPOSITION of KEITH O. REEVES, M.D.,
2 produced as a witness at the instance of the Defendant,
3 and duly sworn, was taken in the above-styled and
4 numbered cause on the 3RD of NOVEMBER, 2014, from 10:01
5 A.M. to 4:36 P.M., before Samantha Downing, CSR, CLR, in
6 and for the State of Texas, reported by machine
7 shorthand, at the offices of THE POTTS LAW FIRM, 100
8 WAUGH DRIVE, SUITE 350, HOUSTON, TEXAS 77007 pursuant to
9 the Federal Rules of Civil Procedure and the provisions
10 stated on the record or attached hereto.

A P P E A R A N C E S

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By: STEVEN J. BORANIAN, ESQ.

ALSO PRESENT:

MR. RODNEY WHITE, VIDEO OPERATOR

REPORTED BY:

MS. SAMANTHA DOWNING, CSR, CLR
TIFFANY ALLEY REPORTING

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EXHIBITS

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#1	9	Notice of Deposition
#2	9	Rule 26 expert report of Keith O. Reeves M.D.
#3	11	Specific expert report on patient Pamela Douglas-Jones
#4	11	Expert report on patient Kristia Groover
#5	12	Expert report on patient Pamela Gruman
#6	12	Expert report on patient Pamela Messer
#7	12	Expert medical report on patient Deborah Villnave
#8	13	Expert medical report on Myra White-Ross
#9	13	Expert medical report on patient Debra Mitchell
#10	30	Table of Contents of the articles
#11	38	Copy of binder
#12	152	SUFU document
#13	164	"Considerations of Surgical Mesh for SUI"
#14	168	Case Report of rectal erosion of synthetic mesh used in posterior colporrhapy

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1	#15	180	Deposition of Frank Zakrzewski
2	#16	188	Material Safety Data Sheet
3	#17	192	MSDS for Marlex polypropylene dated
4			February 15, 1993
5	#18	194	Marlex polypropylene Material Safety Data
6			Sheet from 1997
7	#19	196	Correspondence between the Department of
8			Health & Human Services/FDA and Boston
			Scientific
9	#20	207	"Bowel Cancer and Previous Mesh Surgery"
10	#21	208	Case report of a vaginal leiomyosarcoma
11	#22	209	"Epithelioid Angiosarcoma Associated with
			a Dacron Vascular Graft"
12	#23	210	Excerpts from the IARC Monographs on the
13			Evaluation of Carcinogenic Risks to
			Humans
14	#24	221	Bard Design Input Document
15	#25	228	Design Qualification and Competitive
16			Product Testing for Bard Sling Mesh
17	#26	232	Sheath document
18	#27	235	Table
19	#28	244	Liebert article
20	#29	245	DF Williams 1982, "Review Biodegradation
			of Surgical Polymers"
21	#30	249	Oswald article
22	#31	250	"Characterization of Heavyweight and
23			Lightweight Polypropylene Prosthetic Mesh
			Implants from a Single Patient"
24	#32	261	Clave article
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1	#33	275	de Tayrac article
2	#34	291	Klinge article
3	#35	292	Klinge 1998 study
4	#36	301	Klosterhalfen 2005
5	#37	311	"The Biocompatibility of Prosthetic
6			Meshes"

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1 THE VIDEOGRAPHER: This is tape 1 in the
2 videotaped deposition of Dr. Keith Reeves. Today's date
3 is November 3rd, 2014. We're on the record. The time
4 is 10:01 a.m.

5 Will counsel please identify themselves
6 for the record?

7 MR. POTTS: Derek Potts for the
8 plaintiffs.

9 MR. BORANIAN: Steven Bornanian for
10 defendant, C.R. Bard.

11 THE REPORTER: Okay. Will the witness
12 read and sign?

13 MR. POTTS: Yes.

14 KEITH O. REEVES, M.D.,
15 was called as a witness and, being first duly sworn,
16 testified as follows:

17 EXAMINATION

18 BY MR. BORANIAN:

19 Q. Good morning, Dr. Reeves. My name is Steven
20 Bornanian. I represent C.R. Bard in the cases that
21 we're going to discuss today.

22 We met a moment ago, correct?

23 A. Correct.

24 Q. Now, the videographer said at the outset it's
25 9:01 a.m. It's -- or 10:01 a.m.

1 It's actually 9:01 a.m., correct?

2 **A. Correct.**

3 **This is -- we're on Central Standard**
4 **Time.**

5 Q. Okay. We're here to take your deposition,
6 Doctor.

7 Do you understand that?

8 **A. Yes, I do.**

9 Q. And you've been deposed before?

10 **A. I have.**

11 Q. And about how many times have you been deposed
12 before?

13 **A. I am going to guess probably 25 to 30.**

14 Q. And have you ever given testimony at a
15 deposition as an expert witness?

16 **A. I have.**

17 Q. And of those approximately 25 depositions,
18 roughly how many of them were as an expert witness?

19 **A. Virtually every one of them.**

20 Q. Very well. So we don't need to go through all
21 the ground rules for depositions.

22 The only thing that I would ask is that
23 because the court reporter seated to your right is
24 taking down everything that you and I say, I promise to
25 let you finish your answers before I ask my next

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1 question.

2 And will you also then promise to wait
3 until I am finished before starting your question --
4 answer so she can get it all down?

5 **A. I will.**

6 Q. And if at any point you don't understand one of
7 the questions that I am asking or need clarification,
8 please ask me, and I will try to ask you a better
9 question.

10 Is that fair?

11 **A. That's fair.**

12 (Reeves Exhibit No. 1 was marked.)

13 Q. (BY MR. BORANIAN) Doctor, I am going to mark a
14 few exhibits at the outset here. This is Exhibit 1, and
15 this is the Notice of Deposition for today's deposition.

16 Have you seen this document before?

17 **A. I have not.**

18 (Reeves Exhibit No. 2 was marked.)

19 Q. (BY MR. BORANIAN) Exhibit No. 2, Doctor, is a
20 large document that consists of numerous parts. I
21 probably should have marked this separately, but this is
22 the way it was prepared for me. So bear with me.

23 Do you recognize Exhibit 2, Doctor?

24 **A. I do.**

25 Q. Exhibit 2 is the Rule 26 expert report of

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1 Keith O. Reeves M.D., correct?

2 **A. Correct.**

3 Q. And that's you, correct, Doctor?

4 **A. Yes.**

5 Q. Is this the report that you prepared for this
6 litigation?

7 **A. It is.**

8 Q. I should clarify that.

9 Is this one of the reports that you
10 prepared for the litigation?

11 **A. It is.**

12 Q. And if you turn to the part just behind the
13 first blue page? If you leaf though, Doctor, there's
14 some blue slip sheets in there. Again, I should have
15 marked this separately, but this is the best I have for
16 now.

17 **A. I have opened this up to my CV.**

18 **Is that what you're asking me about?**

19 Q. Yes.

20 Is -- that page that's marked Exhibit A
21 to your report, is that your current Curriculum Vitae?

22 **A. It is.**

23 Q. And if you go to the next one, Doctor,
24 Exhibit B, is that your current fee schedule, Doctor?

25 **A. That is.**

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1 Q. And then Exhibit C, Doctor, is that a list of
2 the materials being relied on in the preparation of this
3 report?

4 A. It is.

5 Q. Doctor, could you leaf through your report,
6 please, and just let me know if this is a true and
7 correct copy of the report that you intend to rely on?

8 A. It is.

9 (Reeves Exhibit No. 3 was marked.)

10 Q. (BY MR. BORANIAN) This is Exhibit 3,
11 Dr. Reeves.

12 Dr. Reeves, have you seen Exhibit 3
13 before?

14 A. I have.

15 Q. And what is this document, Doctor?

16 A. This is my specific expert report on patient
17 Pamela Douglas-Jones.

18 Q. And is this, Doctor, a true and correct copy of
19 that report?

20 A. It is.

21 (Reeves Exhibit No. 4 was marked.)

22 Q. (BY MR. BORANIAN) This is Exhibit 4,
23 Dr. Reeves.

24 Can you tell us what Exhibit 4 is?

25 A. This is my expert report on patient

1 **Kristia Groover.**

2 Q. And is this, Doctor, a true and correct copy of
3 that report?

4 **A. It is.**

5 (Reeves Exhibit No. 5 was marked.)

6 Q. (BY MR. BORANIAN) This is Exhibit 5, Doctor.
7 Can you tell us -- I am sorry.

8 Can you tell us what that is?

9 **A. This is the expert report on patient Pamela**
10 **Gruman.**

11 Q. That's your report, correct?

12 **A. Correct.**

13 Q. And is that a true and correct copy of your
14 report?

15 **A. It is.**

16 (Reeves Exhibit No. 6 was marked.)

17 Q. (BY MR. BORANIAN) This is Exhibit 6, Doctor.
18 Can you please tell us what this is?

19 **A. This is my expert report on patient**
20 **Pamela Messer.**

21 Q. And is Exhibit 6 a true and correct copy of
22 that report, Doctor?

23 **A. Yes.**

24 (Reeves Exhibit No. 7 was marked.)

25 Q. (BY MR. BORANIAN) Here is Exhibit 7.

1 And can you tell us what that is, Doctor?

2 **A. This is my expert medical report on patient**
3 **Deborah Villnave.**

4 Q. And is Exhibit 7 a true and correct copy of
5 that report?

6 **A. It is.**

7 (Reeves Exhibit No. 8 was marked.)

8 Q. (BY MR. BORANIAN) I have just handed you
9 Exhibit 8, Doctor.

10 Can you tell us what that is?

11 **A. My expert medical report on Myra White-Ross.**

12 Q. Is Exhibit 8 a true and correct copy of that
13 report?

14 **A. Yes, it is.**

15 (Reeves Exhibit No. 9 was marked.)

16 Q. (BY MR. BORANIAN) This is Exhibit 9,
17 Dr. Reeves.

18 Can you tell us what that is?

19 **A. My expert medical report on patient**
20 **Debra Mitchell.**

21 MR. BORANIAN: I only have one copy of
22 that.

23 Q. (BY MR. BORANIAN) Is Exhibit 9 a true and
24 correct copy of that report?

25 **A. It is.**

1 Q. Doctor, have I shown you, and have I marked all
2 of the reports that you prepared for this litigation?

3 A. You have.

4 Q. Now, Doctor, in your prior deposition
5 testimony, you mentioned that you have given about
6 25 depositions, virtually all of them as an expert
7 witness; is that correct?

8 A. Correct.

9 Q. Have you ever testified as a nonexpert; for
10 example, as a treating physician?

11 A. Yes, I have.

12 Q. And was that in a case involving claims for
13 product liability?

14 A. It was not.

15 Q. What kind of case was that?

16 A. It was actually a divorce case and I was the
17 treating physician and the issue of sexual fidelity was
18 raised. And I had medical records that spoke to that.

19 Q. Are there any other occasions -- that's quite
20 different from what we have here, isn't it, Doctor?

21 A. Yes, it is.

22 Q. Have you ever had any other occasions where you
23 have testified as a percipient witness as opposed to
24 being an expert witness?

25 A. I have not.

1 Q. So of the times that you have been retained as
2 an expert, do you have any preference whether you work
3 for the plaintiff's side or the defense side?

4 A. As a practical matter of fact, Counselor, I
5 have been on your side 99 percent of the time.

6 Q. So you most often are retained by the defense;
7 is that what you're saying?

8 A. That's correct.

9 Q. Have you ever given testimony at a trial?

10 A. I have.

11 Q. And how many times have you done that?

12 A. I can recall easily three.

13 Q. Were any of those in product liability cases?

14 A. No.

15 Q. What kinds of cases were those?

16 A. One actually was a case in Georgia. I got a
17 call from an attorney's office because I had written a
18 paper on the topic of external cephalic version of
19 babies who were presenting as a breech.

20 In English, it's a process of the
21 obstetrician putting his hands on the pregnant woman's
22 abdominal wall and literally turning a baby from coming
23 butt first to coming head first.

24 And I got a call because the defense
25 counsel read that paper and wanted to know if I would be

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1 willing to come to Georgia to testify in a medical
2 malpractice trial a general practitioner who had done
3 external cephalic version on a patient, and the infant
4 died in utero three days later. And I went to Georgia
5 and testified in that case.

6 Q. How about the other two that you can recall?

7 A. They were med mal. cases, and they were in
8 Houston.

9 Q. For your prior deposition testimony, were any
10 of those in product liability lawsuits?

11 A. They were not.

12 Q. On the whole, were those mainly medical
13 malpractice cases?

14 A. Yes.

15 Q. So your -- I noticed on your business card and
16 on your CV, your current position is emeritus. Is it
17 professor?

18 You have emeritus status, correct?

19 A. I have emeritus status.

20 In December of last year, December the
21 20th, I retired from practice. I maintain my medical
22 license; it's current. I maintain my malpractice
23 insurance. I am maintaining my Board certification with
24 the American Board of Obstetrics & Gynecology.

25 I am just no longer seeing patients in

1 practice.

2 Q. So when you were practicing as an obstetrician
3 and gynecologist -- or you're a gynecologist -- we'll
4 get into that later -- can you estimate what proportion
5 of your time you spent doing medical/legal consultation?

6 A. The bulk of that work was probably done in the
7 years between 1998 and 2007 or 2008.

8 I was appointed as a permanent
9 Physician Member of the Methodist Hospital System here
10 in Houston Board of Directors and I served a five-year
11 term and I voluntarily stopped doing anything in the
12 medical/legal arena because I didn't want to be
13 perceived for taking a position for the hospital one way
14 or the other. So I just stopped all medical/legal
15 activity so I could serve as an independent member of
16 the Methodist Board.

17 Q. And what year was that?

18 A. I was -- I went onto the Board in about 2009,
19 and I stayed on the Board until I retired
20 December the 20th of 2013.

21 Q. So is that how you estimate the 2008 cutoff?

22 A. Yes.

23 Q. Okay.

24 A. I am not absolutely sure about the accuracy of
25 those dates, but that's my best approximation.

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1 Q. Well, estimates are okay --

2 A. Okay.

3 Q. -- for this kind of thing.

4 A. All right.

5 Q. I will ask you to guesstimate one more thing:
6 In terms of percentage, how much of your time were you
7 spending on medical/legal consultation?

8 A. Oh, minuscule.

9 Less than 5 percent.

10 Q. In the cases in which you have been retained as
11 an expert, have any of those involved -- or other than
12 these cases, have any of them involved the implantation
13 of pelvic mesh?

14 A. No.

15 These -- as a matter of fact, Counselor,
16 these cases all preceded the use of pelvic mesh from a
17 -- from a temporal standpoint.

18 Q. The cases in which you were an expert?

19 A. That I testified, yes.

20 Mesh was never an issue, and I don't even
21 think mesh was being used when I was doing most of the
22 work that I did.

23 And most of the cases that I was involved
24 in was obstetric cases, not gynecologic. But I stopped
25 doing obstetrics probably eight years so ago, so I

1 didn't have anything to do with it much after I stopped
2 doing obstetrics.

3 Q. When was surgical mesh introduced to your
4 practice or the areas in which you practice?

5 A. I think we first started seeing it on the scene
6 in 2005, 2006.

7 Q. And when you say, "pelvic mesh," what kinds of
8 mesh are you describing?

9 A. Well, I will tell you that I have never
10 implanted any synthetic mesh with the exception of
11 abdominal sacrocolpopexy. But when the mesh came onto
12 the market, I had previously used some of the cadaveric
13 biologic material and I had also used some Mersilene
14 material, but I have never implanted any of the products
15 that we're going to be talking about later today.

16 Q. So the urethral sling products that we're
17 talking about today, those were introduced in -- in the
18 mid-to-late 1990s, correct?

19 A. Correct.

20 Q. And they remain in use today, correct?

21 A. That is correct.

22 Q. And those are different from the pelvic organ
23 prolapse products that are involved in some of these
24 cases, right?

25 A. Right.

1 Q. Have you been retained by counsel to provide
2 expert testimony in any cases?

3 A. Yes.

4 Q. And those are the seven cases that we've
5 identified here, correct?

6 A. Correct.

7 Q. And for the record, those cases are with the
8 plaintiffs Pamela Douglas-Jones, Deborah Villnave,
9 Pamela Gruman, Debra Ann Mitchell, Kristia Groover, Myra
10 White, or I think you said White-Ross earlier --

11 A. It's a hyphenated last name, yes.

12 Q. -- and Alma Messer.

13 Those seven women, correct?

14 A. Correct.

15 Q. And in the cases in which they have spouses,
16 there are also, you know, loss of consortium claims
17 involved, correct?

18 A. Correct.

19 Q. Are there any other plaintiffs, Doctor, that
20 you've been asked to give an expert opinion on?

21 A. No, sir.

22 Q. And you've also been retained to provide expert
23 testimony on sort of general and generic issues, right?

24 A. Correct.

25 Q. And that's in connection with the Align mesh

1 product, right?

2 **A. Correct.**

3 Q. Have you been retained to provide any other
4 expert opinions in these cases?

5 **A. Not that I am aware of.**

6 Q. Well, hopefully you would be aware of that.

7 **A. I would hope so.**

8 Q. You would insist on payment, I would expect.

9 Have you been retained in any proceedings
10 involving any manufacturers -- when I say,
11 "proceedings," I mean involving vaginal mesh --
12 involving any manufacturer other than C.R. Bard?

13 **A. No, sir.**

14 Q. So you're not giving opinions in any cases
15 involving AMS or Epicon or Endo or any other companies?

16 **A. No, sir.**

17 Q. Take a look at Exhibit 1, Doctor. That's the
18 Notice of Deposition.

19 **A. Is that this?**

20 Q. Correct. The number should be on the sticker
21 down there.

22 **A. I see it. I have got it.**

23 Q. So if you turn to Exhibit A, which is on page 6
24 of Exhibit 1, this is a list of things that we asked you
25 to bring with you to today's deposition.

1 You testified before that you have not
2 seen this before, right?

3 **A. That is correct.**

4 Q. Let's run through these. Hopefully it won't
5 take too long.

6 **A. All right.**

7 Q. No. 1, you have attached your Curriculum Vitae
8 to your expert reports.

9 If you turn to -- well, we looked at that
10 earlier, correct?

11 **A. Yes, we did.**

12 Q. Is that a current copy of your
13 Curriculum Vitae?

14 **A. There may be one paper that was presented at**
15 **the last meeting of the American Urogynecology Society**
16 **that is not on there. And I was the senior author of**
17 **the paper. I was not the presenter at the meeting.**

18 That had to do with the use of urethral
19 stents in uterosacral ligament fixation procedures. I
20 don't think that is germane to the issue that we're
21 going to be talking about today. But I am not sure that
22 that last presentation made it onto the CV.

23 Q. Is there anything else that would be required
24 to bring that CV fully up to date?

25 **A. No, sir.**

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1 Q. No. 2 on Exhibit A there in Exhibit 1, it says,
2 "To the extent not already reflected in your CV, a list
3 of all articles, seminar materials, presentations, et
4 cetera."

5 Is that all included in your CV, Doctor?

6 **A. Yes, it is.**

7 Q. The third one, we've asked for a list of all
8 cases in which you have, during the last four years,
9 provided to the Court or to counsel an Expert Disclosure
10 or report or in which you have given a deposition or
11 testified in court.

12 Doctor, during the last four years, have
13 you provided to the Court or counsel an
14 Expert Disclosure or report?

15 **A. I have not.**

16 Q. And in the last four years, have you given a
17 deposition or testified in court?

18 **A. I have not.**

19 Q. No. 4 requested your complete and entire files
20 for the seven cases on which you've been disclosed as an
21 expert.

22 First of all, what would -- do you
23 understand to be your file when you're talking about
24 these cases?

25 **A. The -- obviously I was not the treating**

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1 physician for any of these ladies.

2 So the only materials that I have were
3 the materials that were provided to me. And in most
4 instances, that consisted of histories and physicals
5 obtained by the treating physicians, Operative Reports,
6 hospital records, and follow-up office visits.

7 Q. Did you prepare any notes, any handwritten
8 notes or typewritten notes?

9 A. Everything I did was done via the computer, and
10 I don't have anything in writing pertaining to these
11 women at all.

12 Q. So when you say everything was via the
13 computer --

14 A. Yeah.

15 Q. -- what do you mean by that?

16 A. That means that I was taking notes in the
17 computer as I was looking at the medical records and
18 putting the material into the computer.

19 Q. And did you bring those notes with you today?

20 A. No.

21 Q. Do you have those notes saved in your computer?

22 A. Probably not.

23 MR. POTTS: Just for the record, Steven,
24 we planned on today being focused on the general side.
25 We can produce all that. But we were so busy getting

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1 the general materials together for you today, but we can
2 get those for you when you're ready to start on those.

3 MR. BORANIAN: Okay. That would be very
4 helpful, whatever notes he's prepared.

5 MR. POTTS: Yeah. I think that's fair
6 game.

7 Q. (BY MR. BORANIAN) So, Doctor, you can work
8 with Mr. Potts and his --

9 A. Yes.

10 Q. -- office to get those notes to us over the
11 course of today.

12 A. I should tell you that there are some
13 handwritten notes -- I want to make that correct --
14 because when these patients were being seen for the
15 medical exams that we did -- and we'll get into this
16 later, but I was actually in the office of Dr. Ricardo
17 Gonzales. He is a urogynecologist.

18 And since I am no longer in practice, I
19 no longer have access to an office. And I was in
20 Ricardo's office, and he and I were taking the history
21 from these women in tandem. I would ask pertinent
22 gynecological questions, and he would ask pertinent
23 urological questions.

24 He has an electronic medical record
25 system that he was using. I was taking notes with my

1 pen and pencil. And those notes do exist. I don't have
2 them with me today.

3 Q. Okay.

4 A. But they exist.

5 Q. If --

6 A. I -- I can get those.

7 Q. I appreciate that.

8 A. Sure.

9 Q. Thank you, Doctor.

10 So you mentioned Dr. Gonzales.

11 You did personally examine a number of
12 these individuals, correct?

13 A. Absolutely, yes.

14 Q. There were five of them, right, that you
15 examined?

16 A. I thought it was seven.

17 I will have to look at the -- you
18 mentioned seven names. I am not -- I will have to look
19 and see.

20 Q. You provided reports on seven individuals,
21 correct?

22 A. Correct.

23 Q. My reading of those reports is that you
24 examined all but two of them, but maybe I am wrong on
25 that. We can go through that in more detail.

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1 A. I would -- we can -- we can go through them one
2 by one. I will recognize what was my work and if I was
3 just extracting from somebody's medical reports versus
4 mine.

5 Q. My reason, though, for asking now is to figure
6 out what -- what the file is, so to speak. And you
7 mentioned your handwritten notes.

8 A. Right.

9 Q. You mentioned your computer notes.

10 You were provided materials, correct?

11 A. Correct.

12 Q. And who provided those to you?

13 A. They came from Mr. Potts' firm.

14 Q. And when -- when you examined the individuals,
15 what you described sort of peaked my interest.

16 So you did the examinations in a
17 different physician's office?

18 A. Yeah.

19 I no longer have an office.

20 Q. Uh-huh.

21 A. So I was working in Dr. Gonzales's office. And
22 he and I together would sit first in his consultation
23 office and he and I would meet the patient, take the
24 patient's history and then the patient would be taken by
25 his nurse to an exam room. And then Ricardo and I went

1 into the exam room to check the patient out.

2 Q. And Dr. Gonzales's notes would be computerized,
3 you think?

4 A. I would assume so.

5 I didn't see him handwrite anything,
6 except at the end of the visit, he would give some of
7 these ladies prescriptions, and he handwrote those,
8 obviously.

9 But almost all of his notes -- I
10 shouldn't say almost.

11 I didn't see him write anything down
12 during the entire course of the time that we were
13 together.

14 Q. So going back to the -- the initial question,
15 so you have your notes, you have computerized notes, you
16 have the information provided by counsel.

17 Is there anything else that you would
18 consider part of your file for these cases?

19 A. I have a compendium of articles that I have
20 read getting ready for this.

21 Q. And that's in this binder sitting in front of
22 you right now?

23 A. Right here.

24 Q. Is that separate and apart from what counsel
25 provided to you?

1 A. **Absolutely.**

2 Q. So who compiled this list -- this compendium of
3 articles?

4 A. These were done -- well, they were done by two
5 people. They were done by me and also by a fellow named
6 Dan McBride, who works for Mr. Potts.

7 THE WITNESS: And, Derek, earlier today I
8 gave you a list of the Table of Contents. I don't know
9 if you still have that or not.

10 A. If you would like, you can have -- this is my
11 list --

12 Q. (BY MR. BORANIAN) So you're handing to me a
13 list --

14 A. A list of the papers that I have in here that I
15 have compiled.

16 Well, you got two copies. One of them is
17 for you.

18 Q. Okay.

19 A. Okay. That's mine. Those were my handwritten
20 notes on these.

21 Q. Okay. I think I'll need both of them,
22 actually.

23 A. As long as I get mine back.

24 Q. Okay. Sure. We can get a copy.

25 A. All right.

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 Q. Okay. So who -- who is Dan McBride?

2 A. The only thing I can tell you is that -- I
3 think he's got the title of Medical Officer for the
4 law firm.

5 Q. Is he an attorney?

6 A. I don't think so.

7 Q. Is he a doctor?

8 A. I think he spent a year or two in medical
9 school, but I don't think he completed medical school.
10 He's not introduced himself to me as a physician.

11 Q. May I see that again, Doctor?

12 A. Sure.

13 Q. Let's mark this marked-up copy as an exhibit.

14 (Brief discussion off the record.)

15 (Reeves Exhibit No. 10 was marked.)

16 MR. POTTS: What Exhibit is that?

17 Q. (BY MR. BORANIAN) This is Exhibit 10,
18 Dr. Reeves.

19 Can you describe for us what Exhibit 10
20 is?

21 A. This is the Table of Contents of the articles
22 that I have compiled in this folder. These are articles
23 primarily -- well, almost exclusively from the medical
24 literature and I have alphabetized them by the last name
25 of the first author and there are some 58 articles

1 listed here.

2 Q. Okay. Let me see that again, Doctor.

3 A. (Tendering document.)

4 Q. And that binder in front of you, have you taken
5 notes in that binder?

6 A. I surely have.

7 Q. Are all of these articles also listed on the
8 Reliance List that we earlier reviewed in Exhibit 2?

9 A. I don't know the answer to that.

10 MR. POTTS: I believe so.

11 Q. (BY MR. BORANIAN) Can I take a look at your
12 binder, Doctor?

13 A. Sure.

14 Q. I may not be able to read the whole thing, but
15 I would like to get an idea of what we're talking about
16 here.

17 A. Help yourself. (Tendering binder.)

18 Q. So how did you go about selecting these
19 articles, Doctor?

20 A. I went into the computer and put in keywords
21 "pelvic mesh," "pelvic organ prolapse."

22 And I should also tell you that in spite
23 of the fact that I am no longer in active practice, I
24 still subscribe to the American Journal of Obstetrics &
25 Gynecology, I subscribe to Obstetrics & Gynecologist,

1 and I prescribe to Female Pelvic Medicine &
2 Reconstructive Surgery. So I -- I see a lot of journals
3 every month.

4 And when I saw something that was germane
5 or pertinent in the articles -- in the journals as they
6 came to me on a month-by-month basis, then I would make
7 a copy of them.

8 Q. Did Mr. McBride aid you with those searches?

9 A. He did.

10 Q. Did she suggest search terms you?

11 A. No.

12 Q. What did he do?

13 A. He just provided me with articles.

14 Q. So you did the searches and you gave him
15 citations and he compiled articles for you?

16 A. And he provided me with some articles, as well.

17 This was a collaborative effort on our
18 parts.

19 Q. Did you and Mr. McBride discuss the articles?

20 A. No.

21 Q. Did you have any correspondence about your
22 collaboration, you and Mr. McBride?

23 A. Only to the extent that he would say, "Here are
24 five more articles. They're attached via Dropbox," or,
25 "They're attached vie" -- "they're attached to the

1 e-mails."

2 But in terms of our having any detailed
3 conversations about the articles, we did not.

4 Q. So you ended up selecting 58 articles for
5 inclusion in this binder; is that right?

6 A. That's correct.

7 Q. And I will note, too, that there are -- there's
8 at least one copy of the Align Instruction for Use in
9 this binder.

10 That's not an article, is it?

11 A. That is correct; that's not -- that's not an
12 article.

13 Q. But a large -- for the most part, these are
14 medical articles, correct?

15 A. Correct.

16 Q. Here is one that is actually 31.1, so is it 59
17 articles?

18 A. It may be 59. Because as big as that binder
19 was, it was possible for one to get stuck to the other,
20 and I didn't realize that I hadn't included them all.

21 So the handwritten copy is the most
22 recent one.

23 Q. Does Exhibit 10 reflect all of the articles
24 that you and Mr. McBride compiled together?

25 A. Yes.

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 Q. So did you go through a process where you
2 reviewed articles and set some aside and put those off
3 and made this binder sort of a final copy, or is this
4 all of them?

5 A. You know, he could have sent me some that I
6 didn't consider to believe germane because they were so
7 essenteric that I couldn't make sense of them, in which
8 case I wouldn't have bothered to put them in there.

9 Q. And did you prepare any notes, Doctor, as you
10 reviewed these articles?

11 A. No.

12 Most of what you see there, you can -- I
13 used a red pen, and I marked what I wanted to be able to
14 refer to quickly.

15 Q. So if all of these articles appear in your
16 Reliance List, the part of Exhibit 2 we've already
17 reviewed, who compiled that list?

18 A. Somebody in Mr. Potts' firm.

19 Q. Did you have any involvement in compiling that
20 Reliance List?

21 A. I did not.

22 Q. So in terms of what you actually relied on,
23 Exhibit 10 is a more accurate, more reliable --

24 A. Is this Exhibit 10?

25 Q. Well, the index is Exhibit 10.

1 A. Yes. That -- yes.

2 If it's not on that list, then I probably
3 have not seen it.

4 Q. So tell me a little bit more about how you
5 found the articles. You mentioned search terms that you
6 used.

7 Any other search terms you used?

8 A. Well, I would look in the bibliography of the
9 article. And if I saw something that I thought was
10 germane, then I would just go to the computer, go to the
11 journal, and print it.

12 Q. And when you were deciding which articles were
13 germane or not, what criteria did you apply?

14 A. How well-known was the journal, was it in
15 English, would I be able to read it, where was it from,
16 did I know the authors.

17 Obviously some journals carry a lot more
18 weight than others. And if I thought that it was an
19 insignificant journal or an -- or somebody that I
20 haven't heard of -- and I haven't -- I am not going to
21 begin to tell you that I am familiar with all these
22 authors, but at least I could see where the papers came
23 from and whether or not I felt they were pertinent.

24 Q. So other than the documents that were provided
25 to you and your notes --

1 **A. Yes.**

2 Q. -- and this binder, is there anything else that
3 you consider to be part of your file --

4 **A. No.**

5 Q. -- for those cases?

6 MR. POTTS: Counsel, just to be clear for
7 the record, you keep saying, "for these cases."

8 The way we organized this is we have a
9 group of materials that were his general opinions, and
10 that's what we focused on today. Then we have separate
11 files for each of the plaintiffs.

12 So I assume when you say, "these files,"
13 you're encompassing all of those?

14 MR. BORANIAN: Sure. And I read that
15 there's some ambiguity here.

16 Q. (BY MR. BORANIAN) When I am talking about
17 these case, I am talking about the whole ball of wax,
18 Doctor.

19 **A. The same thing.**

20 Q. When say generic -- are there separate files or
21 binders for each of the individual patients?

22 **A. No.**

23 Q. So, for example, when you received medical
24 records or deposition testimony regarding an individual
25 patient, is that kept separately in your file?

1 A. Oh, I -- I misunderstood you. I am sorry.

2 Yes. And I gave all that information
3 yesterday to Mr. Potts. I no longer have that in my
4 possession.

5 Q. Okay. We'll go over that a little later, I
6 think.

7 A. Yes.

8 Q. But in terms of the -- the opinions and the
9 analysis of such issues as, you know, contraction and
10 shrinkage and certain generic issues, this -- this
11 binder is the key thing, right?

12 A. What you see is what you get.

13 Q. Did you examine any medical devises, any mesh
14 products?

15 A. Yes.

16 Q. And is that on the Reliance List, as well,
17 having received those products?

18 A. Well, physically, I had a copy of the Align
19 product. Derek had one of those in his office. He
20 showed it to me. I looked at it.

21 I don't have that with me, if that's your
22 question, but I have looked at the Align product.

23 MR. POTTS: It's down the hall.

24 Q. (BY MR. BORANIAN) And you held that product in
25 your hand, correct?

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 **A. Yes.**

2 Q. And you mention that in your report, correct?

3 **A. I don't know that I mention it in the report**
4 **that I held it in my hand, but the answer to your**
5 **question is yes.**

6 Q. And have you examined or manipulated or looked
7 at any other medical device for the purpose of forming
8 your opinions?

9 **A. I have not.**

10 Q. Okay. Doctor, what I think we'll do is we'll
11 mark this binder as Exhibit 11.

12 (Reeves Exhibit No. 11 was marked.)

13 Q. (BY MR. BORANIAN) So Exhibit 10 is the index,
14 and the binder is 11.

15 **A. Okay.**

16 Q. And I'll -- I will return custody of this
17 binder to you, but we need to get a copy of it, okay?

18 MR. POTTS: Yes.

19 MR. BORANIAN: Do you have a service we
20 can use overnight or something?

21 MR. POTTS: Sure.

22 **A. I think we're going to deforest half of East**
23 **Texas with all these copies.**

24 Q. (BY MR. BORANIAN) Well, that -- that's an
25 occupational hazard of our line of work, Doctor.

1 **A. I understand.**

2 MR. BORANIAN: And the Doctor may want to
3 refer to this.

4 MR. POTTS: Do you want me to make a
5 copy?

6 MR. BORANIAN: At the next break.

7 MR. POTTS: At the next break, I'll make
8 a copy.

9 MR. BORANIAN: Yeah.

10 Q. (BY MR. BORANIAN) So we're still on Exhibit 4,
11 Doctor, on Exhibit A.

12 **A. All right.**

13 Q. Have we reviewed -- well, there's a whole pile
14 of documents over on the credenza to your left, Doctor.

15 Describe what that is.

16 **A. I saw that for the first time at 8:00 o'clock**
17 **this morning.**

18 Q. And is it your understanding that that is a
19 copy of everything that is cited in your Reliance List,
20 Exhibit 2?

21 **A. Yes.**

22 But understand, I did not go through
23 every page of those documents since I arrived this
24 morning.

25 Q. The -- the documents you actually did go

1 through are in Exhibit 11, correct?

2 **A. Correct.**

3 MR. POTTS: Well, he's reviewed other
4 documents that are not in Exhibit 11.

5 **THE WITNESS: Yes.**

6 MR. POTTS: The documents are depositions
7 and other things he's reviewed over time.

8 MR. BORANIAN: Okay.

9 Q. (BY MR. BORANIAN) So you reviewed deposition
10 testimony, correct?

11 **A. Correct.**

12 Q. And you relied on -- on testimony both in
13 forming your generic opinions and also your
14 case-specific opinions, correct?

15 **A. Correct.**

16 Q. So where have you maintained the testimony that
17 you have reviewed for your general or generic opinions?

18 **A. The deposition testimony was sent to me online,
19 and I read that deposition testimony from my computer.**

20 Q. And who sent that to you?

21 **A. Mr. Potts.**

22 Q. And how about for the case-specific opinions,
23 such as treating physicians or the plaintiffs
24 themselves; did you receive that online, as well?

25 **A. Some of that was sent to me as hard copy, and I**

1 gave that back to Mr. Potts yesterday. Some of it came
2 online. Most of that was hard copy.

3 Q. And describe to me your file-keeping process
4 for those case-specific opinions. You said you gave it
5 to Mr. Potts.

6 In what form did you maintain the
7 records?

8 A. I -- I had a specific manila folder for each
9 patient. And I kept Patient A stuff in a folder,
10 Patient B stuff in a folder, and so forth and so on.

11 Q. So seven folders, right?

12 A. Correct.

13 Q. And are the contents of those folders the
14 complete file for those seven individuals?

15 A. They're everything I received, if that answers
16 your question.

17 I didn't -- I didn't get anything that I
18 tossed.

19 Q. So explain that a little further. You received
20 documents.

21 Did you review all the documents you
22 received?

23 A. Yes, I did.

24 Q. And all of that went into those folders, right?

25 A. That is correct.

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 Q. Did you do any additional document gathering or
2 information gathering for those seven individuals?

3 A. No.

4 Q. So what you were provided by Mr. Potts' law
5 firm constitutes the universe of information about those
6 individuals, correct?

7 A. Correct.

8 Q. And we can take a look at those folders, you
9 know, later, even tomorrow, but did -- were you provided
10 entire deposition transcripts or excerpts of
11 depositions?

12 A. I had the entire depositions.

13 Q. Were they all available?

14 Were there any treating physicians whose
15 transcripts were not available yet?

16 A. I don't know the answer to that question.

17 I will tell you -- now, if you're talking
18 depositions, I didn't see the depositions of any
19 treating physicians. The depositions that I saw were
20 the depositions of Bard employees.

21 MR. POTTS: Once again, we're moving
22 between case specific and general.

23 But you're talking about treating
24 physicians' depos in the seven plaintiffs' cases?

25 MR. BORANIAN: Correct.

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 **A. Yeah. I didn't see any depositions from**
2 **treating physicians.**

3 Q. (BY MR. BORANIAN) Did you see any depositions
4 for individual plaintiffs, either women or their
5 husbands?

6 **A. No.**

7 Q. So all the depositions that you saw, whether
8 for generic opinions or specific opinions, all of them
9 were of Bard employees, right?

10 **A. To the best of my knowledge, that is correct.**

11 Q. Was there any trial testimony in that package?

12 **A. No.**

13 Q. So -- and you were given the entire transcript,
14 correct?

15 Is that correct?

16 **A. As far as I know, yes, sir.**

17 Q. Okay. But we would be able to look in your
18 folder and see?

19 **A. You can look at those packets that I have for**
20 **each patient and confirm that, yes.**

21 Q. Except that the -- and I am sorry to beat a
22 dead horse here, but it's important.

23 Except the depositions of the Bard
24 employees, those were given to you electronically,
25 correct?

1 **A. Correct.**

2 Q. And were they sent to you as an e-mail
3 attachment or online in Dropbox; do you know?

4 **A. Both.**

5 Q. And do you have those e-mails in your system?

6 **A. No.**

7 MR. POTTS: We also reviewed depositions
8 in person together.

9 **THE WITNESS: Yes.**

10 Q. (BY MR. BORANIAN) I am sorry. I didn't hear
11 what you said.

12 **A. He said that he and I reviewed some depositions**
13 **in person together.**

14 I can specifically recall one that he and
15 I went over. The fella's last name was Bracken,
16 B-r-a-c-k-e-n. Derek and I went over that deposition in
17 his office.

18 Q. Are all the depositions that you reviewed
19 listed in your reliance materials in Exhibit 2?

20 **A. I assume, yes.**

21 **Again, I didn't see that entire**
22 **Reliance List, so I can't tell you that definitively.**

23 Q. Is there anything else that we haven't
24 discussed that would constitute your file for either
25 your general opinions or your case-specific opinions?

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 **A. No, sir.**

2 **I think you've covered it very well.**

3 **Q. Do you have any correspondence with Mr. Potts'**
4 **law firm or with any of the individual plaintiffs?**

5 **A. No.**

6 **Q. No e-mails, no letters, nothing?**

7 **A. No.**

8 **Q. You mentioned earlier that Mr. McBride sent you**
9 **e-mails saying, "Dear Dr. Reeves, here are five**
10 **articles," things like that?**

11 **A. That's correct.**

12 **Q. So that's an example of correspondence with**
13 **Mr. Potts' law firm asking about --**

14 **A. Some of those articles, I got as recently as**
15 **Thursday or Friday, and I do have the last e-mail in my**
16 **computer from Dan McBride saying, "Here are five more**
17 **articles you may want to read before the depositions**
18 **Monday and Tuesday."**

19 **Q. So have you had other written communications**
20 **with counsel?**

21 **A. If you mean e-mail, the answer to that is yes.**

22 **And I have also sent statements, invoices**
23 **to Mr. Potts, and I have copies of those, if you would**
24 **like to see those.**

25 **Q. We -- I am getting to that.**

1 **A. Okay. All right.**

2 Q. That's No. 6 on the list here.

3 **A. All right.**

4 Q. Did -- when you sent e-mails or received
5 e-mails from Mr. Potts or his colleagues, where are
6 those e-mails now?

7 **A. In cyberspace.**

8 Q. But they're retrievable, correct?

9 **A. I doubt it.**

10 I don't think so, unless McBride kept
11 copies of them. I certainly didn't.

12 Q. Have those e-mails been printed and included in
13 any of the materials that are present here today?

14 **A. I don't know that.**

15 I didn't print any of them.

16 Q. So why do you think the e-mails are no longer
17 available, then?

18 **A. They were simply saying, "Reeves, here are five
19 articles you may wish to have."**

20 And I read the articles. If I wanted
21 them, I printed them, and then I deleted the e-mail. I
22 didn't see any reason to keep it.

23 Q. Okay. So other than e-mails from Mr. McBride,
24 have there been any other e-mails with Mr. Potts' law
25 firm?

1 **A. No.**

2 Q. Have there been any other e-mails with any of
3 the attorneys -- any attorneys representing any pelvic
4 mesh plaintiff?

5 **A. No.**

6 Q. So it's really those e-mails from Mr. McBride
7 saying, "Here are articles"?

8 **A. Correct.**

9 Q. Nothing of any substance, correspondence by
10 mail or e-mail?

11 **A. No.**

12 Q. When you met with the individual plaintiffs,
13 were there any audio recordings made?

14 **A. No.**

15 Q. So any record of that meeting or those meetings
16 would be represented by handwritten or typed-written
17 notes, correct?

18 **A. Correct.**

19 Q. Do you have a letter -- we would call it an
20 engagement letter.

21 Do you have a letter from any attorneys,
22 including Mr. Potts, laying out the terms of your
23 engagement and how much you would be paid and so on and
24 so forth?

25 **A. We simply had a verbal agreement.**

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 Q. Now, I will ask you again. The answer is
2 probably the same.

3 Have we gone over everything that you
4 consider to be your file in these cases?

5 A. Yes, sir.

6 Q. Do you ever advertise your services as an
7 expert?

8 A. No.

9 Q. Do you work with any sort of expert broker
10 firms, firms that help law firms and businesses find
11 various experts?

12 A. No.

13 Q. Do you have your invoices that you have sent to
14 Mr. Potts for these cases?

15 A. I can produce those for you. I don't have them
16 in my back pocket.

17 Q. Okay. We'll need those, Doctor.

18 A. Okay.

19 Q. If you can please get those?

20 A. Sure.

21 THE WITNESS: Derek, will you remind me
22 to produce those?

23 MR. POTTS: We'll get them together this
24 evening.

25 THE WITNESS: Okay. All right.

In Re: C.R. Bard (200)

Keith Reeves, M.D.

11/03/2014

1 Q. (BY MR. BORANIAN) Did you make any drawings,
2 models, or illustrations, Doctor?

3 A. No, sir.

4 Q. To the extent you're relying on your medical
5 observations and your examination of the plaintiffs, is
6 everything in those notes that you described?

7 A. Yes.

8 Q. So you didn't do -- well, you no longer have a
9 medical practice, right?

10 A. Correct.

11 Q. So we wouldn't look in your medical practice
12 for files on those patients, would we?

13 A. They do not exist.

14 Q. So we've discussed, Doctor, all information,
15 documents, or anything else that you claim support your
16 opinions in these cases?

17 A. Yes.

18 Q. Okay. We can put that aside for now.

19 So to review, we are going to get your
20 invoices, and we're going to get your notes from the
21 examinations?

22 A. Yes.

23 Q. Anything else you were going to get?

24 MR. POTTS: I will grab the device here
25 on the next break and bring it in here.

1 MR. BORANIAN: Okay.

2 MR. POTTS: But we'll produce each one of
3 the separate files as he described them here shortly.

4 Q. (BY MR. BORANIAN) Doctor, we marked as
5 Exhibits 2 through 9, I believe, the expert reports.

6 Do those reports contain complete
7 statements of all the opinions that you hold with
8 respect to C.R. Bard pelvic mesh products and these
9 seven plaintiffs?

10 A. It depends on how you define, "complete."

11 I think these are the reports that I
12 wrote for the purpose of this litigation on these
13 patients, and they -- they contain the opinions that I
14 have. I don't think that I have any significant
15 opinions that I have not included.

16 Q. Do the reports in your view completely and
17 adequately state the bases for your opinions?

18 A. Yes.

19 Q. When you testify at trial in this case, will
20 you testify -- do you intend to testify to the opinions
21 set forth in your reports?

22 A. If asked, yes.

23 Q. Okay. Those opinions for the generic portion
24 of your opinions concern the Bard Align product,
25 correct?

1 **A. Correct.**

2 Q. Do you have any opinions with regard to the
3 Bard Avaulta Solo or Avaulta Plus product?

4 **A. I do.**

5 Q. But you don't intend to give those as part of
6 your generic or general opinions, correct?

7 **A. Not if we're talking about Align.**

8 Q. Well, you have only been -- you have only
9 described opinions in connection with the Align product
10 in your report, correct?

11 **A. Correct.**

12 Q. And those are all the general opinions you
13 intend to give, correct?

14 **A. Correct.**

15 Q. When were you retained as an expert by
16 Mr. Potts' firm?

17 **A. I am going to give you my best guesstimate, and**
18 **I think I first got involved with him in the spring of**
19 **this year, probably in March or April.**

20 Q. And that's 2014?

21 **A. Correct.**

22 Q. And your rate is \$500 per hour, correct?

23 **A. Correct.**

24 Q. Do you have any premiums in your rate schedule,
25 for example, for trial testimony or -- or other kinds of

1 testimony?

2 A. No.

3 Q. Who first approached you to work with Mr. Potts
4 on these cases?

5 A. Derek himself did, I think.

6 Q. And describe how that interaction came about.

7 A. As I was telling Derek earlier today, I am
8 surrounded by attorneys in my family. My brother-in-law
9 is a Houston attorney named Mark Kerrigan, and he works
10 a lot with a fellow named Steven Kherkher from
11 Williams Kherkher.

12 When my brother-in-law retired, he
13 realized I had done a lot of work with pelvic mesh in
14 the last several years of my practice. He introduced me
15 to Steve Kherkher, and then Steve introduced me to
16 Derek.

17 Q. And when did that interaction take place?

18 A. Probably in the earlier part of this year,
19 February or March of 2014.

20 Q. Had you had prior experience with the
21 Potts Law Firm?

22 A. No.

23 Q. Now, we don't have your invoices here, Doctor,
24 but can you estimate how much time you've spent on this
25 engagement?

1 **A. Before this morning, probably between 65 and 70**
2 **hours.**

3 Q. And does that include the work that you did
4 forming case-specific opinions?

5 **A. Yes.**

6 Q. When we get your invoices, other than this
7 morning and today and tomorrow, is there any time that
8 is -- that will not be reflected on those invoices?

9 **A. No, sir.**

10 Q. So time -- you mentioned that you had articles
11 as recently as Thursday.

12 Time you spent in the last few days, will
13 that be on the invoices?

14 **A. It will.**

15 Q. Is it possible, Doctor, to estimate how much
16 time you've spent forming your general opinions versus
17 how much time you've spent forming your case-specific
18 opinions?

19 **A. No.**

20 Q. Can you estimate what you've spent a greater
21 amount of time on, general versus case specific?

22 **A. That's splitting hairs.**

23 I don't think I can. I am not trying to
24 be obstinate. I just don't have any idea.

25 Q. If there's one that's -- we'll move on.

1 We'll take a look at the invoices and see
2 if they illuminate anything.

3 **A. Okay.**

4 Q. So if you take a look at the Reliance List,
5 which is Exhibit C to Exhibit 2, this was compiled by
6 counsel, correct? That's Exhibit -- that's a different
7 exhibit, Doctor.

8 Look at Exhibit 2, Doctor, which is the
9 big fat one?

10 **A. Right here? This one?**

11 Q. No. It has a sticker on the corner that says
12 2. Here it is.

13 **A. Okay. Your page is which?**

14 Q. Exhibit C.

15 **A. Exhibit C.**

16 Q. It's the Reliance List. It's the last thing
17 there.

18 **A. All right. I see it.**

19 Q. So this was provided by counsel, right?

20 **A. Correct.**

21 **I didn't have anything to do with the**
22 **creation of this list.**

23 Q. So to the extent you did your own research,
24 that -- that's reflected in your binder, Exhibit 11,
25 right?

1 **A. Right.**

2 Q. Did you -- did counsel actually send you copies
3 of all of the items that are listed in Exhibit C of
4 Exhibit 2?

5 **A. They did not.**

6 Q. So are there items on here that you have not
7 reviewed at all?

8 **A. Absolutely.**

9 Q. So if I wanted to figure out what you've
10 actually looked at and what you haven't, I could look at
11 your report and look at your citations, right?

12 **A. And you could cross-reference this list with**
13 **that list.**

14 Q. So Exhibit 10 is the list of articles that you
15 laid eyeballs on?

16 **A. That you can unequivocally say, yes, Reeves**
17 **read these.**

18 Q. And if it's not on Exhibit 10, Dr. Reeves
19 didn't look at it, right?

20 **A. That's a reasonably safe assumption.**

21 Q. How about the citation to documents and
22 articles actually in your report, Exhibit 2; did you
23 look at those things?

24 **A. Not necessarily.**

25 **I didn't see all of those.**

1 Q. Okay. So really Exhibit 10 and 11, that's --
2 that's what you looked at, right?

3 A. Correct.

4 Now, that's in addition to my general
5 medical knowledge, and I reference that every day of the
6 week.

7 Q. Sure. We'll let you describe that in a little
8 bit.

9 A. Okay.

10 Q. Did you have any opinion on whether the list of
11 materials provided by counsel was an adequate list of --
12 of reliance documents?

13 A. I think it's exhaustive.

14 Q. And Exhibit 10 and 11, those are we think a
15 subset of -- of the Reliance List; is that true?

16 A. I do not -- this -- this was -- I did this
17 yesterday --

18 Q. Okay.

19 A. -- okay? So Potts has not seen them until this
20 morning.

21 But I thought for my benefit I wanted to
22 go through and make sure that if you were going to ask
23 me specific information that I wanted you to be able to
24 tell me, "Reeves, I am asking you a question about this
25 article."

1 And I wanted to be sure that I could flip
2 to exactly what you were asking about me about, so made
3 this yesterday for my benefit. And I figured if I make
4 a copy for me, I'll make a copy for you.

5 Q. I appreciate that, Doctor.

6 A. You're welcome.

7 Q. After reviewing -- well, did you ever review
8 Exhibit C?

9 A. I saw Exhibit C for the first time this
10 morning.

11 Q. So did you request any information from the
12 Potts Law Firm? We have gone over you worked with
13 Mr. McBride to get articles.

14 Was there any other request for
15 information from Mr. Potts' office?

16 A. No.

17 Q. It all just arrived?

18 They decided what to send you?

19 A. Yes, I think that's a safe thing to say.

20 Q. Now --

21 A. I want to expand on that, if I may.

22 Q. Sure.

23 A. McBride had done a lot of work in journals that
24 I didn't have access to and he had looked at specific
25 mesh characteristics in material science journals that I

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1 had no experience with and he provided me with some
2 articles that I would have had no way of accessing.

3 And I -- I said, "Derek" -- I said,
4 "Daniel, if there's information about mesh that you have
5 that I wouldn't otherwise know about, please send that
6 to me."

7 To that extent, I did request
8 information. But many, if not most, of the articles
9 that he sent me on the characteristics of mesh that
10 didn't come from medical journals was provided to me by
11 Dan McBride.

12 MR. POTTS: Can we take a break when you
13 get to a point?

14 MR. BORANIAN: Now is good.

15 THE VIDEOGRAPHER: We are off the record.
16 The time is 10:02 a.m.

17 (Recess from 10:02 a.m. to 10:15 a.m.)

18 THE VIDEOGRAPHER: We are back on the
19 record. The time is 10:15 a.m.

20 Q. (BY MR. BORANIAN) Dr. Reeves, for the
21 depositions of the Bard employees that you reviewed,
22 please describe to me the process through which you
23 received those transcripts and reviewed them.

24 A. They came to me as e-mails, and I printed them.
25 And -- or in some instances, I just read them directly

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1 off of my computer. I think in most instances, now that
2 I think about them, I read them off my computer.

3 I don't think I can produce a copy of
4 those depositions now. I didn't bring anything with me
5 that consisted of those depositions. I read them
6 online.

7 Q. So did you print them, or not?

8 A. No, I don't think so.

9 Q. Okay. So you read them all online?

10 A. Yes.

11 Q. And when you did that, were you doing it alone?

12 A. For the Bracken deposition, Derek and I went
13 over that together at one point.

14 The others that I read -- and I can't
15 remember them by name. But I just had those sent to me
16 online, and I read them online.

17 Q. So other than the Bracken deposition, did you
18 collaboratively read depositions with counsel?

19 A. No.

20 Q. And when you received the depositions, other
21 than the Bracken deposition, did counsel suggest to you
22 any portions that you ought to read?

23 A. No.

24 I read everything. I read the whole ball
25 of wax.

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1 MR. POTTS: And he needs to clarify
2 something from the prior testimony this morning.

3 A. If I could, I think I told you incorrectly that
4 I had never seen this before; this material list, I
5 think you called it.

6 Q. (BY MR. BORANIAN) Exhibit C to Exhibit 2?

7 A. That's actually in the report that I've
8 submitted and signed. So, yes, I had seen this before.
9 I just didn't recognize it for whatever reason in this
10 format.

11 As I look through this list of articles,
12 as I said to you earlier, there are some articles in
13 here that are not in here, and there are some articles
14 in here that are not in here.

15 But I have seen this list of articles
16 before, and I want to make sure that's on the record.

17 MR. POTTS: Just to clarify, if you read
18 the top of the Reliance List, we were exhaustive. This
19 list is everything he may rely on through trial.

20 It's report, deposition, and trial, so
21 it's an exhaustive Reliance List, as we believe the
22 Court expects in this case.

23 Q. (BY MR. BORANIAN) Okay. Well, Doctor, you
24 have formed opinions, correct?

25 A. That is correct.

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1 Q. What I am trying to explore is the materials
2 that you relied on in forming those opinions and the
3 bases for these opinions. That's the endgame here,
4 Doctor.

5 So when you're referring to -- you were
6 mentioning, "here," and, "there," and gesturing.

7 So you're comparing your index,
8 Exhibit 10, to the list that's in Exhibit 2 -- Exhibit C
9 of Exhibit 2, right?

10 A. Right.

11 Q. And is it your testimony, Doctor, that there
12 are some documents listed on Exhibit 10 that are not in
13 Exhibit 2?

14 A. The numbers are confusing me, but let me
15 clarify that there are some articles in here --

16 Q. In your binder?

17 A. -- in my binder that, for instance, do not show
18 up in Exhibit C.

19 Q. Okay.

20 A. And there are certainly some articles that are
21 listed in Exhibit C that are not copied and in this
22 binder --

23 Q. Okay.

24 A. -- okay?

25 Q. Just to clarify for the fourth time, the binder

1 is what you rely on, right?

2 **A. Primarily, but not exclusively.**

3 Q. Well, what do you mean by that?

4 **A. Well, there are some articles listed here in**
5 **Exhibit C, yes, that are not in the binder that I read.**

6 Q. And did you rely on those articles in forming
7 your opinions?

8 **A. Sure.**

9 Q. So if I wanted to figure out which articles in
10 Exhibit C, your Reliance List --

11 **A. Yes.**

12 Q. -- which articles did you rely on in Exhibit C
13 that are not in your binder?

14 **A. I can't answer that question.**

15 Q. You can't answer that question?

16 **A. No.**

17 Q. How would -- how would we determine the answer
18 to that question?

19 **A. You could go through these, I guess, article by**
20 **article and say, "Reeves, did you read this," and I can**
21 **say, "Yes, I did," or, "No, I didn't," and we could see**
22 **if it's on the list.**

23 **I don't know how else to do it.**

24 Q. Okay.

25 **A. I am not trying to be difficult. I am just**

1 **telling you that --**

2 Q. So your testimony is that the binder is
3 primarily what you relied on?

4 A. **That is correct.**

5 MR. POTTS: In terms of medical
6 literature, right?

7 **THE WITNESS: Right.**

8 Q. (BY MR. BORANIAN) So when did you meet with
9 Mr. Potts about the Bracken deposition?

10 A. **You could probably find that out by looking at**
11 **the invoices. I cannot tell you that I remember that**
12 **date specifically.**

13 Q. Do you remember how long ago it was?

14 A. **It was probably in September.**

15 Q. And what did you and he discuss about the
16 Bracken deposition?

17 A. **I don't have any -- we went through it page by**
18 **page.**

19 **I don't have any specific recollection**
20 **about anything specifically in that deposition.**

21 Q. How about generally speaking; what did you
22 discuss about the Bracken deposition?

23 A. **We discussed about what Bard knew and when they**
24 **knew it and what kind of design changes were indicated**
25 **in the Align product and the fact that there had been a**

1 **significant degree of complaints issued; as I recall,**
2 **some 197 complaints about the devices that they were**
3 **aware of. But that at the time of that deposition,**
4 **as -- according to Bracken's recollection, there have**
5 **not been any design changes in the product.**

6 Q. So you were reviewing the Bracken deposition to
7 draw an inference about what Bard knew and when Bard
8 knew it; is that fair to say?

9 MR. POTTS: Objection; form.

10 **THE WITNESS: Could you read that**
11 **question back to me, please, ma'am?**

12 (Requested portion was read.)

13 A. **That's fair to say.**

14 Q. (BY MR. BORANIAN) And you did not read any
15 physicians' depositions; is that correct?

16 A. **That's correct.**

17 Q. Did you contact or speak with any of the
18 treating physicians?

19 A. **No.**

20 Q. Did you feel like you would need to read their
21 depositions or speak with them about forming your
22 opinions?

23 A. **No.**

24 Q. And why is that?

25 A. **Because the medical records and the fact that I**

1 took my own history, and the fact that Ricardo Gonzales
2 and I examined these patients is all the information I
3 needed to come up with my opinion.

4 Q. And that goes for all the opinions that are
5 case specific?

6 A. Yes.

7 Q. Did you review any expert reports from any
8 other experts in these pelvic mesh cases, in any pelvic
9 mesh case?

10 A. No.

11 Q. Have you reviewed Dr. Gonzales' reports?

12 A. No.

13 Q. Have you reviewed any depositions of any
14 experts in any pelvic mesh case?

15 A. No.

16 Q. Have you reviewed any trial testimony from any
17 pelvic mesh case?

18 A. No.

19 Q. I have in my notes to ask you how you went
20 about selecting scientific articles, but we've gone
21 through that, haven't we, Doctor?

22 A. I think we have.

23 Q. When you were searching for articles, did you
24 look for and consider articles that were on both sides
25 of the issue?

1 **A. Absolutely.**

2 **In fact, several of them are.**

3 **Q. Several of them in the binder?**

4 **A. Yes.**

5 **Q. So you looked for and considered articles that**
6 **are contrary to the opinions you are giving today,**
7 **correct?**

8 **A. Correct.**

9 **Q. Describe to me how your report -- and let's**
10 **start with Exhibit 2, which is the big fat report in**
11 **front of you.**

12 **Describe to me how that report was**
13 **prepared.**

14 **A. The best word that I can use is to say that**
15 **this was a collaborative effort.**

16 **I wrote -- for instance, my**
17 **qualifications are verbatim in my own writing. A lot of**
18 **this information is something that was done with**
19 **exchanging one draft to another and I would write and**
20 **send it to Potts and/or to McBride and they would edit**
21 **and send back to me and I would edit theirs.**

22 **The information that they had**
23 **specifically from Bard that I had not seen is a lot of**
24 **their work.**

25 **All of the medical information in here is**

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1 absolutely mine.

2 Q. Other than Mr. Potts and Mr. McBride, were
3 there any other people you collaborated with in -- in
4 preparing your reports?

5 A. I don't know to what extent Mr. Barfield had
6 anything to do with this report. You would have to ask
7 him that.

8 To the best of my knowledge, it was Derek
9 and Dan McBride. And I don't know how much of this Dan
10 was involved with the writing, nor can I tell you how
11 much Derek had to do with it.

12 I reserved the right going in to change
13 anything that I didn't agree with if I was going to put
14 my signature on it.

15 Q. Because you're signing it, right?

16 A. Absolutely.

17 Q. So is it fair to say that the material with
18 regard to Bard's knowledge and conduct and the citations
19 to Bard's documents was primarily the work of Mr. Potts
20 and his colleagues?

21 MR. POTTS: Objection; form.

22 A. I think yes.

23 Q. (BY MR. BORANIAN) And then by that same
24 virtue, the discussion of medical issues, for example,
25 in the case-specific reports when you're giving medical

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1 opinions, that's primarily your work?

2 A. Yes.

3 I can give you one specific example, and
4 we'll get to this in the case-specific reports: There
5 is a phrase to initiate several things that says on or
6 about -- and I am going to pick a random date.

7 "On or about October 15th, 2012, this
8 patient was seen."

9 I would never phrase it like that. She
10 was either seen on October 15th, or she wasn't. I
11 wouldn't say, "On or about."

12 That's not my verbiage. I don't think
13 physicians speak like that, but obviously lawyers do.

14 Q. Well, we'll be guilty to that one.

15 A. All right.

16 Q. Why don't you turn to your Curriculum Vitae,
17 Doctor, which is Exhibit A to Exhibit 2? It's in that
18 big fat thing you've got there.

19 A. Got it.

20 Q. So, Doctor, please state your full name for the
21 record.

22 A. Keith Reeves.

23 Q. Have you ever gone by any other names?

24 A. Well, my middle initial is O. So in college, I
25 was, "KO."

1 Q. What is your occupation, and what kind of
2 doctor are you?

3 A. I am now retired.

4 I was in practice as an
5 obstetrician/gynecologist, and I practiced gynecology
6 only for the last seven or eight years that I was in
7 practice.

8 Q. And you retired in December of last year,
9 correct?

10 A. Correct.

11 Q. So for the -- for the seven or eight years
12 preceding your retirement, that was exclusively as a
13 gynecologist?

14 A. Correct.

15 Q. Are you, or were you a urogynecologist?

16 A. No.

17 Q. Are you a member of the
18 American Urogynecology Society?

19 A. Yes.

20 I am considered emeritus. I don't have
21 to pay the same dues that they do because I am no longer
22 in practice.

23 Q. And that's referred to as a --

24 A. Life. That's AUGS, yes, A-U-G-S.

25 Q. You were saying, Doctor?

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1 A. I was -- I was -- I thought you were going to
2 ask what kind of membership is that, and I think it's a
3 life membership.

4 Q. What's your current address?

5 A. 4846 McDermott Drive, Houston, 77035.

6 Q. And before you retired, what was your position,
7 the last position you held?

8 A. I was the Founding Medical Director of the
9 Methodist Hospital Center For Restorative Pelvic
10 Medicine. I also had the title of Professor of Clinical
11 Obstetrics & Gynecology at Weill Cornell Medical School,
12 which is located in New York City.

13 Q. So where would I find your employment history
14 on your Curriculum Vitae?

15 A. You don't have that, but I can recount it for
16 you very easily.

17 Q. Okay.

18 A. I was in private practice from 1976 until
19 September of probably 2010. And in September of 2010, I
20 sold my practice to the Methodist Hospital.

21 And from '10 until I retired, for the
22 last 3-and-half years that I was in practice, I was
23 employed by the Methodist Hospital, and the specific
24 employer was the Methodist Hospital Physicians
25 Organization.

1 Hospitals in the state of Texas cannot
2 legally own physician practices, and they set up a
3 corporate entity on their Organizational Chart that I
4 could be employed by but not be working directly for the
5 hospital.

6 Q. So in your private practice from 1976 to
7 September of 2010, what was the nature of your practice?

8 A. General obstetrics and gynecology. Except for
9 the last three years of that before I went to work for
10 the hospital, I had stopped doing obstetrics, and it was
11 gynecology only.

12 Q. So you weren't delivering babies anymore?

13 A. Correct.

14 And thank God.

15 Q. Have you delivered a lot of babies, Doctor?

16 A. About 7500.

17 Q. Do you currently maintain any hospital
18 privileges?

19 A. I do not.

20 Q. And where did you last maintain hospital
21 privileges?

22 A. Methodist here in Houston.

23 And in the Methodist Medical Center,
24 there are now five Methodist hospitals around the city
25 and Southeast Texas, and I was on staff only at

1 **Methodist in the Medical Center.**

2 Q. So can you clarify that, Doctor?

3 Does that mean you were -- had privileges
4 at all of those hospitals --

5 A. No.

6 Q. -- or just the Medical Center?

7 A. No. **Just the opposite.**

8 **I was only on the staff at Methodist**
9 **Medical Center.**

10 Q. Have you ever had your hospital privileges
11 suspended or revoked?

12 A. No.

13 Q. Are you currently a licensed physician?

14 A. **I am.**

15 Q. In Texas?

16 A. **Yes.**

17 Q. Anywhere else?

18 A. No.

19 Q. Have you passed any Boards?

20 A. **Yes.**

21 Q. Are you Board certified?

22 A. **Yes.**

23 Q. In what?

24 A. **Obstetrics and gynecology.**

25 Q. Have you been certified in pelvic

1 reconstruction?

2 A. No.

3 You're talking about female pelvic
4 medicine and reconstructive surgery.

5 Q. Yes.

6 A. The answer to that is no.

7 May I elaborate?

8 Q. Sure.

9 A. That Board didn't come into existence and start
10 offering the examinations until 2013.

11 Q. Right.

12 A. And you're agreeing with me, and I think that's
13 the right date. So we're on the same page here.

14 The Board gave people like me the option
15 of becoming grandfathered in urogynecology, and that
16 would have required several things for those of us who
17 were in practice long before fellowships came into
18 existence. I would have had to have passed an
19 examination. I would have to demonstrate that over half
20 of the surgical procedures that I was doing were of the
21 urogynecologic nature. I would have easily qualified in
22 that regard.

23 The other thing that they specified was
24 that over 50 percent of my clinic work, my in-office
25 work would have been urogynecology. And in the month of

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1 May of 2012, I actually kept a running list of every
2 patient that I saw, and only about 35 or 40 percent of
3 my patients were specifically urogynecology.

4 And I would have had to have told 60
5 percent of my patients coming in to see me, "I can't see
6 you anymore because I am doing only urogynecology."

7 And Methodist wouldn't have wanted that
8 to happen from an economic standpoint.

9 So I made the decision that -- knowing
10 that I was going to retire when I was in my 70th year,
11 it wasn't worth get that many patients alienated. So I
12 decided not to sit for the examination and become a
13 urogynecologist so I could claim to be so.

14 I have never billed myself as being
15 anything other than a gynecologist and one that does a
16 lot of vaginal surgery.

17 Q. So of the -- you mentioned that 35 percent of
18 your patients were in urogynecology?

19 A. Correct.

20 Q. The other 65 were general gynecology?

21 A. Exactly.

22 MR. POTTS: I will object. That
23 misstates the prior testimony.

24 He said a third in the office.

25 A. Yeah.

1 I said of the surgery that I was doing in
2 the last several years that I was in practice, that was
3 almost exclusively -- 85 to 90 percent -- in the realm
4 of urogynecology.

5 The office patient population, women
6 coming in for their annual gynecological examination,
7 those were probably 60 percent, and 35 to 40 percent
8 were of the urogynecologic nature.

9 Q. (BY MR. BORANIAN) Okay. I wanted to clarify
10 that.

11 A. All right.

12 Q. And just to clarify also, when I was agreeing
13 with you, I don't know the exact date when the Board
14 became available.

15 A. Okay.

16 Q. But I know it was recent.

17 A. It is.

18 Q. And you're also recently retired. That much, I
19 know.

20 So describe to me, Doctor, your surgical
21 practice before you retired.

22 A. I was doing an awful lot of pelvic
23 reconstructive surgery. Women would come in to see me
24 for pelvic organ prolapse. I was doing a lot of vaginal
25 hysterectomies. I was doing a lot of uterosacral

1 ligament fixation procedures and working in conjunction
2 with urologists and colon rectal surgeons and plastic
3 surgeons.

4 I would guess that probably 20 to 25
5 percent of my surgery was involved in removing vaginal
6 mesh and vaginal slings.

7 Q. In the final year of your practice, about how
8 many procedures were you doing, however you want to
9 measure it, per week, per month?

10 A. Per week? I was probably doing four -- three
11 to four major cases a week for the last year I was in
12 practice.

13 Q. And when you say, "major case," what do you
14 mean by that?

15 A. Something that would be as involved as a
16 vaginal hysterectomy plus a uterosacral ligament
17 fixation plus anterior/posterior colporrhaphy.

18 Q. So that estimate of you said three to four
19 major cases a week --

20 A. Correct.

21 Q. -- is -- that estimate, would that apply to
22 prior years in your practice, as well?

23 A. Yes.

24 Q. So pretty consistent?

25 A. Yes.

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1 Q. Can you tell us a bit about your educational
2 background, Doctor?

3 A. I did my undergraduate work at UT Austin. I
4 was there '62 through '66. I graduated Cum Laude.

5 And when I went to Baylor College of
6 Medicine here in Houston from '66 through '70. I
7 graduated with an M.D. in '70.

8 I did an internship in pediatrics from
9 July 1st of '70 through June the 30th of '71.

10 I was in Air Force as a flight surgeon
11 for 2 years from '71 to '73.

12 Then I came back to Baylor to do on
13 OB/Gyn residency from '73 to '76.

14 Q. And in 1976, that's when you started your
15 private practice, correct?

16 A. In July of '76, correct.

17 Q. Did you do any fellowships?

18 A. No.

19 Q. So I notice in your CV, as a flight surgeon,
20 you were part of the Aerospace Medicine Office, correct?

21 A. That's it.

22 I was the -- the -- there were two
23 physicians in the Flight Surgeon's Office, and the
24 senior person was always the chief. And the second year
25 that I was there, I was the senior guy, so I was the

1 Chief of Aerospace Medicine at Sheppard Air Force Base
2 in Wichita Falls, Texas.

3 Q. So from '71 to '73, did you treat any
4 astronauts there, Doctor?

5 A. No.

6 Q. Are you currently on the faculty of any medical
7 school?

8 A. Not any longer.

9 Q. Were you at one time?

10 A. Yes.

11 Q. And which one or ones?

12 A. I was the -- I was Professor of Clinical
13 Obstetrics and Gynecology at Cornell and
14 Clinical Associate Professor at Baylor.

15 Q. And when did you hold that position at Cornell?

16 A. I was appointed in 2005 when Baylor -- I am
17 sorry -- when Methodist and Cornell were affiliated.

18 Q. So were you able to serve in that position
19 while living here in Houston?

20 A. Yes.

21 Q. So you didn't have to go to New York for that,
22 true?

23 A. True.

24 Q. Okay. And then when were you a
25 Clinical Professor at Baylor?

1 A. I was never Clinical Professor.

2 I started out as an instructor at Baylor
3 in '76 and continued through at that rank through my
4 retirement.

5 And we don't have enough time day or
6 tomorrow or the rest of the week to ask about what
7 happened with Baylor and Methodist. That was a nasty
8 divorce, but we don't want to go there.

9 Q. So it says here in your CV, Doctor, that you
10 were Clinical Associate Professor until 2005 with
11 Baylor College of Medicine.

12 Is that true?

13 A. Yeah.

14 And I honestly don't know whether that
15 continued once I affiliated with Cornell. Once the
16 Baylor/Methodist divorce occurred, we no longer had
17 Baylor students or residents rotating through
18 Methodist Hospital.

19 Q. So then in 2005 through December 2013, that's
20 when you became a --

21 A. Professor.

22 Q. -- professor -- a Clinical Professor of OB/GYN
23 at Cornell, right?

24 A. Correct.

25 Q. And that's because of the combinations you're

1 describing to us that are complicated, right?

2 A. Correct.

3 Q. Do you want to get into that today, Doctor?

4 A. You don't have that much time, Counselor.

5 Q. You are the Founding Medical Director of the
6 Methodist Center for Restorative Pelvic Medicine, true?

7 A. True.

8 Q. Describe to me what the Methodist Center for
9 Restorative Pelvic Medicine is, Doctor.

10 A. It became obviously to me in the early 2000s
11 that several things were happening: Number one, we were
12 having a huge increase in the number of women who were
13 developing pelvic organ prolapse as the Baby Boomers got
14 further along in age.

15 And it also became obvious to me that the
16 information that I had learned in residency, while it
17 was superb, was not answering the problems that we were
18 having, because 11 percent of the population -- of the
19 female population is estimated to need pelvic organ
20 prolapse surgery in their lifetime.

21 And I knew that as a gynecologist, I
22 couldn't bring everything to the table that those women
23 were going to need. And I looked around my own practice
24 and I was working a lot with urologists and I was
25 working a lot with colon rectal surgeons and also with

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1 plastic surgeons. And we would work together and
2 coalesce to solve a particular patient's problem.

3 And it seemed to me that there were other
4 places around the country that had put together
5 Pelvic Floor Centers, for lack of a better term. And I
6 said, "We need one of these in Houston."

7 So I went to the administration, and I
8 said, "I need your permission to do this. I am going to
9 need Methodist Hospital funding, and I am going to need
10 Methodist Hospital support."

11 And I presented this to hospital
12 administration, and they said, "Go for it."

13 So they gave us money for a Clinical
14 Coordinator. They marketed us very heavily. They
15 publicized us with Methodist Hospital periodicals, and
16 they helped make it happen.

17 I took physicians who were practicing
18 with me to meet colleagues around the Southeast Texas
19 and said, "We're here, and we're here to handle the
20 stuff that you don't want to tackle."

21 And I had taught an awful lot of
22 residents in the years that I had been in practice, and
23 they knew to send me the complicated stuff and the tough
24 stuff they didn't want to handle. And we became known
25 as the place to go in Southeast Texas if you had a

1 problem other people couldn't handle.

2 Q. Did you model your center after the
3 Pelvic Floor Center that you're describing?

4 A. I didn't visit any of those, but I knew, for
5 instance, what places like the Cleveland Clinic had
6 done.

7 And when I went to the annual AUGS
8 meetings, then I would determine what places in other
9 folks were doing.

10 The University of Michigan has a
11 profoundly strong program.

12 And the other thing that happened that
13 was very beneficial is I operated on a woman who shall
14 remain nameless, obviously. And her family had been a
15 former member of the Methodist Hospital staff. And
16 three months after I operated on her for pelvic organ
17 prolapse, they gave an endowment to the
18 Methodist Hospital. And they said, "Reeves, you're in
19 charge of this."

20 So I funded electrosurgery with that money,
21 and it's now probably seven or eight years old. And we
22 -- I was able to cherry pick some of the best-known
23 names in urogynecology from the country to come to
24 Methodist every year and give that lecture.

25 Q. So how did patients -- well, I say, "did."

1 But does the center still run?

2 A. Absolutely.

3 Q. But you retired from there in December,
4 correct?

5 A. Correct.

6 Q. So -- and when you were the Medical Director,
7 how were patients typically referred to the center?

8 A. They were -- they would call the center. They
9 would have a telephone number. And we bent over
10 backwards -- I should -- I didn't tell you this earlier,
11 but we bent over backward to make sure that people that
12 were working for the hospital like I was were treated
13 equally with people who were in private practice.

14 And the Clinic Coordinator actually kept
15 a list of physicians by specialty and by area of
16 interest, so that when a patient called and didn't have
17 a physician in mind, she said, "Well, let me first line
18 you up to see a urologist, because it sounds like your
19 problem is primarily urological."

20 And we tried to keep the center members
21 balanced in terms of the referrals that they received so
22 that nobody can come and say, "You're not playing fair
23 because you've got me listed as a member of the center,
24 but I am not getting any referrals."

25 And that persists to this day to the best

1 of my knowledge. People would call up. They would
2 describe briefly to the Clinic Coordinator the problem
3 they were having, and the Clinic Coordinator would say,
4 "I am going to align you up initially to see this
5 doctor."

6 She could take enough of a history over
7 the telephone, since these people in many instances were
8 coming a great distance to see us, she would have them
9 lined up to see two or three different specialties on a
10 given day.

11 And then if it was determined that they
12 needed surgery, then all of us would operate at one time
13 on the same patient.

14 Q. So when you say treating members of the
15 Methodist staff as compared -- you're referring to
16 referrals to those practitioners, correct?

17 A. Correct.

18 Q. What were your responsibilities as the
19 Medical Director?

20 A. I was responsible for recruiting the people who
21 I wanted to be in the center to begin with.

22 And the word that we used was actually
23 originated with Dr. Tim Boone, who is still the current
24 Chairman of Methodist Urology. And Tim said, "You ought
25 to put people in this center who do a preponderance" --

1 was his word -- "of their work in pelvic organ
2 prolapse."

3 So, for instance, the urologists who were
4 members of the center, we're not going to include
5 somebody that does primarily male prostate work. We
6 didn't need those guys in the center, although we did
7 include some people because we wanted males to feel
8 comfortable if we had a male that had a problem with
9 excessive radiation therapy who developed fistulas in
10 the rectum, then that would involve the Colon Rectal
11 Surgery Service and the Urology Service to treat those
12 guys.

13 Q. So recruiting the talent?

14 A. I recruited the talent.

15 Q. Anything else?

16 A. Yes.

17 We also would have a quarterly case
18 conference which interesting cases would be presented,
19 and we also started probably four years ago a
20 fellowship. It's not officially approved yet, because
21 we don't have a urogynecologist on the faculty now who
22 has been in practice for five years.

23 We have urogynecologists in the center,
24 but none have been in practice for five years. You
25 can't be approved for a fellowship until you have

1 somebody with that degree of experience. So our
2 fellowship only lasts for one year.

3 The plans are to extend that to a full
4 three-year fellowship when our urogynecologists who are
5 there now have enough time and grade to do that.

6 I was actively involved in teaching these
7 people. In spite of the fact that I cannot and should
8 not call myself a urogynecologists, I am teaching the
9 Fellows how do it, as well as the colon rectal surgeons
10 and the urologists and the other people.

11 Also, I should add this: We have a Ph.D.
12 pelvic floor physical therapist, and there are only
13 about 30 people who have that qualification in the
14 entire United States. They're rare, and we have one at
15 Methodist.

16 Q. Okay. So you did recruiting, and you did the
17 quarterly case conference.

18 Fair to say you were teaching Fellows?

19 A. Absolutely.

20 Every time I went to the operating room,
21 I would have a Fellow with me. And in most instances,
22 at that level of training and experience, the Fellows
23 are doing the surgery, and we're first assisting them.

24 Q. So what were your other responsibilities as
25 Medical Director?

1 A. If anybody needed to be called on the carpet,
2 if there were problems, that came to my desk, and I
3 continued to work with the administration to make sure
4 that we had adequate funding.

5 Q. Was that last part time consuming?

6 A. I would meet with the Vice President who was
7 responsible on at least a monthly basis, if not two or
8 three times a month. Sometimes it was as simple as a
9 telephone call.

10 But I would say that administratively 10
11 percent of my time was involved as the Medical Director
12 of the center.

13 Q. Did you continue to treat patients?

14 A. Absolutely.

15 Q. When did you last treat patients?

16 A. December the 20th of --

17 Q. Of 2013?

18 A. Yes.

19 Q. So you saw patients throughout your time as
20 Medical Director?

21 A. Oh, yeah.

22 Q. So when I had in my notes that you were in
23 private practice until September 2010, what does that
24 mean?

25 A. That means that September 1st of 2010, I was

1 employed by Methodist Hospital Physicians Organization,
2 and I -- it was just a change in title as far as the
3 patients were concerned.

4 Q. Okay.

5 A. The office didn't change. But on that date,
6 Methodist Hospital owned the furniture, fixtures, and
7 equipment.

8 Q. Okay. So you were still a practicing OB/GYN?

9 A. Yes. I was still in practice; I was just
10 employed by the hospital.

11 I was going to get a check every month
12 come rain or come shine from the hospital, but I was not
13 going to be sending out bills to the patients as
14 Keith O. Reeves. That bill was going to come from the
15 Methodist Hospital Physicians Organization.

16 Q. Okay. I got it.

17 And by that time, you were a gynecologist
18 exclusively, right?

19 A. Yes.

20 Q. So I may have already asked you this, but in
21 terms of treating patients, what were you doing the last
22 year of your practice?

23 What was the nature of your practice the
24 last year?

25 A. I would be in the clinic seeing patients

1 probably two and a half to three days a week. And the
2 rest of the time, I would be in the operating room.

3 Q. Does that describe a typical week throughout
4 your time as Medical Director?

5 A. Yes.

6 Q. Are you currently doing any teaching?

7 A. No.

8 Q. Have you -- well, let me break this down.

9 At the -- at the center, do you do
10 medical research?

11 A. Yes.

12 Q. And can you describe that to me?

13 A. Yes.

14 The article, as I said, was not listed on
15 the CV. It describes the last paper that I was
16 significantly involved in. And we were looking to see
17 if putting a stent in the ureters at the time of
18 uterosacral ligament fixation would keep us from
19 unintentionally involving the ureters when we did that
20 operation.

21 The literature has shown consistently
22 that because there's such close proximity between the
23 uterosacral ligament and the ureter, there's a 9 to 11
24 percent potential for unintentionally involving the
25 ureters in that process. And we presented at the last

1 AUGS meeting 96 cases, and probably 75 of those cases
2 were mine as the operating surgeon to see if putting the
3 stent in made a difference. As it turns out, it didn't,
4 which is kind of surprising.

5 But -- so I was actively involved in
6 recruiting those patients, operating on those patients,
7 and helping to write the paper and getting it ready for
8 presentation.

9 I did not present the paper, but I am
10 listed as the last author. And that's the position for
11 the senior author of the paper.

12 Q. Was that a clinical study?

13 A. Yes.

14 Q. And can you describe how the study was
15 designed?

16 A. It was a randomized prospective trial. The
17 patient consented to it, and it obviously was not
18 double-blinded; it couldn't have been. It was
19 randomized and it was controlled and it was a clinical
20 trial. And patients consented to it.

21 Q. So some patients got the stents, and some
22 didn't?

23 A. Correct.

24 Q. Have you done any other research or published
25 any other articles?

1 **A. Yes.**

2 Q. Have you published any articles or given any
3 presentations pertinent to the vaginal mesh products
4 like the Align sling?

5 **A. No.**

6 Q. Have you published any papers or given any
7 presentations pertinent to vaginal mesh products like
8 the Avaulta pelvic organ prolapse products?

9 **A. No.**

10 Q. Have you published any papers or given any
11 presentations relating to the repair of pelvic organ
12 prolapse?

13 **A. No.**

14 I do have one that's listed in the CV.
15 And I think the lead author was then one of our Fellows
16 named Eric Hercado having to do with a woman who had a
17 huge problem.

18 Yeah, Hercado. Randy Bailey was the
19 colon rectal surgeon, and this was in the International
20 Urogynecology Journal: Rectal Erosion of Synthetic Mesh
21 Used in Posterior Colporrhaphy Requiring Surgical
22 Removal.

23 Q. And that was a Case Report, right?

24 **A. That was a case report, right.**

25 Q. Okay. Any studies involving pelvic organ

1 prolapse that you've done?

2 **A. Other than the one I mentioned to you with**
3 **regard to the stents.**

4 Q. Okay. So is the stent paper the only one study
5 you've ever done?

6 **A. No.**

7 **I mean, I have got a whole list of --**

8 Q. Right.

9 **A. Right.**

10 **But that's the only published study or**
11 **paper that's been presented -- publication is still**
12 **pending -- the only published study involving anything**
13 **in the field of urogynecology.**

14 Q. Okay. Have you ever done -- published a paper
15 or given a presentation on the treatment of
16 stress urinary incontinence?

17 **A. No.**

18 Q. Are you on the Editorial Board of any journals
19 or publications?

20 **A. I am not.**

21 Q. Have you been?

22 **A. No.**

23 Q. What are the publications that you consider to
24 be most authoritative in your field?

25 **A. Do you mean journals when you say,**

1 "publications"?

2 Q. I do.

3 A. Okay. I would say -- I would list Obstetrics &
4 Gynecology, The American Journal of Obstetrics &
5 Gynecology, and Female Pelvic Medicine & Reconstructive
6 Surgery. That's the official AUGS journal.

7 Q. Have you ever consulted for C.R. Bard?

8 A. No.

9 Q. Have you ever done any consulting for any other
10 medical device company?

11 A. When I first got involved in using the
12 biological graft materials, Repliform and Xenform, those
13 were Boston Scientific products, and I worked a lot with
14 their detail man in the field. But I never was employed
15 by them, and I never got a paycheck from
16 Boston Scientific.

17 I also went to a training session for AMS
18 up in Minnesota. They were trying to recruit me to get
19 involved with their Apogee and Perigee systems, but I
20 was not willing to do so after going to that training
21 session.

22 Q. Let me ask you about the Boston Scientific
23 involvement that you described.

24 When was that? Approximates are okay.

25 A. Okay. I am going to go back and say it was in

1 the early 2000s, probably 2004, 2005. That's my best
2 guess.

3 I certainly wouldn't want to be held to
4 that.

5 Q. And you worked primarily with the -- what you
6 call the detail man, the sales representative, right?

7 A. Correct.

8 Q. And what was the nature of that work?

9 A. I was not very happy with the results that I
10 was getting using traditional surgical technique. It's
11 just that when we're doing that, 70 percent of the
12 time -- only 70 percent of the time were those
13 procedures successful, and I wanted to see if I couldn't
14 get a better success rate.

15 Q. And when you describe procedures, what are you
16 talking about?

17 A. I am talking about anterior and posterior
18 colporrhaphy and support of the vaginal apex.

19 So I thought I would try using some
20 biological material and see if that would make any
21 difference. And I used the biologic products for
22 probably 18 month to 2 years, and I came away with the
23 impression that they were, number one, very expensive
24 and, number two, that my results were not any better, so
25 I stopped using them.

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1 Q. So when you say you were working with the sales
2 representative, what exactly do you mean by that?

3 Were you using the products and providing
4 feedback to him or her or --

5 A. Yes. I would --

6 Q. You described using the products, but how was
7 that a collaboration with -- with Boston Scientific in
8 any way?

9 A. Well, there were not a lot of people in Houston
10 at the time who were doing that, and they wanted to see
11 if I would start doing this and then start speaking for
12 them, being a part of their Speakers' Bureau.

13 And I -- I used it long enough to say
14 that I am not comfortable talking for you because I
15 don't think it's any better than anything else out
16 there.

17 Q. And those were biologic products, correct?

18 A. Correct.

19 Q. So that was not a synthetic mesh product; is
20 that right?

21 A. That is correct.

22 Q. Now, describe to me your interaction with AMS
23 when they were trying to approach you to do something.

24 A. Yeah.

25 They had me come up to, I think it's

1 Minnetonka, Minnesota. I am not sure about that name.

2 That's home -- headquarters for them.

3 I went up there for a weekend training
4 session and saw what they were doing and saw how the
5 product was being used, and they said, "Would you like
6 to start doing these for us? And we'll fly you around
7 the country and let you do training for us."

8 And I said, "I am not interested."

9 Q. Can you estimate when that was?

10 A. Again, the early 2000s.

11 Q. So before you said 2004, 2005 roughly --

12 A. Roughly.

13 Q. -- for Boston Scientific.

14 Was that -- was that before or after the
15 AMS?

16 A. Boston Scientific was probably before AMS. AMS
17 was probably after that.

18 Q. So AMS in the 2005 time frame; is that fair to
19 say?

20 A. That's a good guess.

21 Q. Describe to us the Apogee and Perigee products.

22 What are those?

23 A. Those are synthetic mesh products that are
24 placed in the anterior and posterior vaginal walls.

25 Q. So that was not a urethral sling, right?

1 A. No.

2 Q. And the Boston Scientific product was not a
3 urethral sling; is that right?

4 A. That is correct.

5 Q. And why did you in the end have reservations
6 about speaking for AMS?

7 A. AMS did not have any randomized prospective
8 clinical trials demonstrating the safety and the
9 efficacy of their device, nor did any other
10 manufacturer, including Bard.

11 Bard and other companies that put these
12 devices on the market went through the 510 process, and
13 they did not get FDA approval. They only obtained FDA
14 clearance.

15 I was trained as a scientist and I was
16 trained to use the Scientific Method and I was trained
17 to rely on experimental and scientific evidence that
18 demonstrates the safety and efficacy of a product.

19 And in my best medical opinion, these
20 companies have simply not done that. They piggybacked
21 on Marlex and the abdominal use for Marlex in hernia
22 repair to bring these products onto the market, trying
23 to show that they were substantially equivalent to the
24 products that were used on the abdominal wall.

25 And as a gynecologist, I am very

1 comfortable telling you that the abdominal wall and the
2 vagina are not the same thing.

3 And the science that these companies were
4 using was, for lack of a better term, trying to say that
5 they were one and the same, and I simply do not and did
6 not believe that.

7 Q. Now, the AMS product that you -- or products
8 that you referred to were for anterior and posterior
9 repair, correct?

10 A. Correct.

11 And they also claim, and I am not -- I
12 will also tell you, Counselor, that with the exception
13 of using some Marlex for abdominal sacral colporrhaphy,
14 I have never placed any synthetic product in the vagina,
15 period.

16 And with regards to Apogee and Perigee, I
17 don't claim any particular expertise with those devices,
18 other than that I have from removing them. And I have
19 taken a ton of this stuff out, but I have never put any
20 of it in.

21 Q. Except for abdominal colporrhaphy, correct?

22 A. Correct.

23 Q. And how many times have you used abdominal mesh
24 for the ASC procedure?

25 A. I have probably done 10 or 12 of those cases.

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1 Q. And that was using synthetic polypropylene
2 mesh; is that right?

3 A. Correct.

4 If I can elaborate, what's unique about
5 that operation is the fact that that mesh is covered up
6 after it's put into place. The mesh is sown to the apex
7 of the vagina, and then we either tunnel or open the
8 posterior peritoneum and go all the way up to the
9 sacrum, the anterior part of the backbone, and sew that
10 mesh into the sacral promontory. Then the peritoneum is
11 used to completely cover that mesh up so that there's no
12 exposure of the mesh to any of the intestinal -- so any
13 of the intestines.

14 It's not going to be able to erode onto
15 the large intestine or the small intestine. It's not
16 going to be able to involve anything in the pelvis
17 because it's literally behind the pelvis when it's
18 properly put in place.

19 Q. What are some of the risks involved in the
20 abdominal colpopexy procedure?

21 A. It's a major surgical procedure.

22 And like any others, it is going to be
23 potentially complicated by infection, by failure of the
24 wound to heal. There's the possibility of a clotting
25 phenomenon. There's the possibility of hemorrhage after

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1 the fact. I would say that those are the major
2 complications.

3 It's also got the potential for the mesh
4 to erode through the apex of the vagina where it's sown
5 into the vagina. I will say those are the major
6 complications.

7 Q. And mesh erosion is a complication of any
8 procedure involving the implantation of surgical mesh,
9 correct?

10 A. Correct.

11 Q. And is mesh erosion also a complication of
12 procedures when you implant biologic products?

13 A. Probably not in the same sense, because the
14 biologic -- biologic products are designed to be gone
15 usually within 6 to 18 months of their being implanted,
16 and the only thing they will have left behind is the
17 potential for the body to infiltrate that tissue and
18 re-infiltrate it.

19 I have never seen a biologic product that
20 has eroded.

21 Q. But it is possible, and it is a complication of
22 the implantation of biologic products that the -- the
23 product itself will become exposed through the vaginal
24 wall, correct?

25 MR. POTTS: Objection; asked and

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1 answered.

2 A. Yeah.

3 I would suspect there are some people who
4 have had that happen. That's not anything that I would
5 tell a patient preoperatively as part of my informed
6 consent session, "Ms. Jones, this is -- you have the
7 significant potential for this product to erode through
8 your vaginal wall."

9 And the other thing about that is that
10 this a biological product, and it's going to degrade
11 after having been in the pelvis. It's not designed to
12 stick around for any length of time at all.

13 If you were to go back and operate on
14 these patients 12 months later, 18 months later you're
15 not going to find any evidence of the biologic product.
16 It will be gone.

17 So erosion is really not a problem with
18 the biological products.

19 Q. (BY MR. BORANIAN) So you have given us some
20 thoughts on the pelvic floor products, the A/P repair
21 products.

22 Would you agree that the urethral sling
23 products, when they were introduced, were supported by a
24 substantial body of medical literature?

25 MR. POTTS: Objection; form, vague and

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1 ambiguous, overbroad.

2 **A. I would say that there is a good body of**
3 **evidence now supporting their efficacy.**

4 And there was a reasonable degree of
5 evidence when they first came onto the market for those
6 specific products, yes.

7 Q. (BY MR. BORANIAN) Well, we'll come back to
8 that, Doctor, when we're going through your opinions.

9 We were talking about whether you had
10 worked for medical device manufacturers, and you
11 mentioned Boston Scientific, although no money changed
12 hands, correct?

13 **A. Correct.**

14 Q. And for AMS, I presume that they reimbursed you
15 expenses for your travel to Minnetonka, correct?

16 **A. Correct.**

17 Q. Was there any other remuneration involved in
18 your dance with AMS?

19 **A. I never did anything with them, so no.**

20 Q. No.

21 Have you consulted for any other medical
22 device manufacturer?

23 **A. No.**

24 I think you have listed there that I was
25 on the Speakers' Bureau for Wyeth, but they're a not a

1 -- they're -- that was for Premarin for hormone therapy.

2 Q. Right.

3 A. It was not medical device.

4 Q. That's my next question.

5 Have you ever consulted with any drug
6 companies?

7 A. Yes.

8 Q. And that would be Wyeth?

9 A. Yes.

10 Q. And you were a speaker on behalf of Premarin?

11 A. Yes.

12 Q. Any other involvement with drug companies?

13 A. No.

14 Q. Did your involvement with Wyeth affect in any
15 way your integrity as a physician?

16 A. No.

17 Q. So you would agree that -- that
18 highly-qualified doctors like yourself from time to time
19 consult with medical device manufacturers and drug
20 companies, right?

21 A. Yes, sir.

22 Q. And there's nothing wrong with that, is there?

23 A. I don't think so.

24 Q. Have you ever designed a medical device?

25 A. I have.

1 Q. And what was that?

2 A. As part of the uterosacral ligament fixation
3 procedure, I devised a right-angle Allis clamp that
4 makes it much easier to grasp a uterosacral ligament
5 when we're putting the sutures into it. That's made --
6 that's made by Marine Midland Medical. It's a Florida
7 company.

8 I also worked with a company here in
9 Houston that was named Mylex, and they sold out to
10 somebody else. But I came up with some devices to put
11 onto the Lone Star retractor, which is used to open up
12 the vagina introitus to work inside the vagina, and I
13 came up with some clips and some springs to go onto the
14 Lonestar retractor to facilitate the surgical procedure.

15 I also came up with the idea -- and this
16 stopped once I retired, because I wasn't going to be
17 involved with the hospital any longer. But I went to a
18 party at an AUGS meeting. And for party favors, they
19 gave away these sticks that you can break and shake.
20 You see them in Halloween, and they start glowing.

21 I came up with an idea for some -- some
22 of this product to be put into urethral stents so that
23 we could put stents into the ureters and be able to see
24 them at the time of surgery. There are lighted stents
25 on the market that use fiber-optic technology, but those

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1 are \$1500 a case, and they're used once and tossed.

2 The devices that you wear around your
3 neck on Halloween are \$2 and 50 cents a piece. I was
4 seeing this as something that would be patentable and
5 would make my retirement extremely comfortable, but it
6 didn't work out because I retired, and I wasn't going to
7 fund what it would take to get it through the FDA.

8 To get a product like that through the
9 FDA would take a quarter-of-a-million dollars, so it's
10 lying fallow.

11 Q. So an inexpensive glowing urethral stick?

12 A. Correct.

13 Q. And did you do any testing on the safety of
14 implanting this Halloween party favor into human bodies?

15 A. Only in cadaver.

16 Q. Where did you do the testing?

17 A. Actually in two places: We did it in the
18 Methodist Hospital laboratories, and I also went over to
19 the UT cadaver labs. I used both of the medical schools

20 Q. So implantation in cadavers is an accepted way
21 of assessing a product's efficacy and safety, correct?

22 MR. POTTS: Objection; form, overbroad
23 and ambiguous.

24 A. I don't think you can easily assess safety in a
25 cadaver. How do you know if you hurt it or not?

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1 But I think from an efficacy standpoint,
2 we wanted to see with these lighted stents using the
3 energy that is generated from chemoluminescence if these
4 things would be effective in a cadaver pelvis.

5 And it probably was not at the time using
6 enough -- there was not enough light energy to see it
7 easily.

8 Q. And what kind of testing would you have done to
9 assess the safety of this proposed device?

10 Animal testing, for example?

11 A. Oh, yeah.

12 We also used it -- in the Methodist labs,
13 they have -- they have a pig lab, and we were putting
14 this in live pigs that were just about to be -- the
15 Cardiovascular Surgery Service had finished with the
16 heart in the pig, and we got the leftovers.

17 And we would go over when they were
18 finished, and I could put these stents into the pig
19 ureters.

20 Q. So animal testing is -- is usually a first step
21 in determining the safety of an implantable device,
22 right?

23 MR. POTTS: Objection; overbroad, vague,
24 and ambiguous.

25 A. It would certainly be on my list of things to

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1 **do first.**

2 Q. (BY MR. BORANIAN) And animal testing is a
3 sound and legitimate way to assess the safety of an
4 implantable medical device, right?

5 MR. POTTS: Same objection.

6 **A. That depends on the animal you're using. I**
7 **think you would have to ask me very case-specific**
8 **instances.**

9 I would say is animal testing widely used
10 in the field of medical devices? Yes. Can you easily
11 extrapolate animal results to humans? No.

12 Q. It is one of the principal ways in which
13 researchers today assess the safety of implanted medical
14 devices, correct?

15 **A. Correct.**

16 Q. Okay. I am told that we need to change tapes,
17 so let's take a break.

18 **A. Sounds good.**

19 THE VIDEOGRAPHER: We are off the record.
20 The time is 11:15 a.m.

21 (Recess from 11:15 a.m. to 11:27 a.m.)

22 THE VIDEOGRAPHER: This is the beginning
23 of tape 2. We are back on the record. The time is
24 11:27 a.m.

25 Q. (BY MR. BORANIAN) Doctor, before I forget,

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1 Mr. Potts has currently brought into the room what's
2 been represented to me as a product that you have seen
3 and held.

4 Is that true, Doctor?

5 **A. That's true.**

6 Q. And this one is an Align RS Retropubic/Supra
7 Pubic Urethral System; is that right?

8 **A. That's right.**

9 Q. And this one has a product number of HUXK1176.

10 Did I read that correctly, Doctor, the
11 black number there on the sticker?

12 **A. Yes.**

13 Q. And it is a box with an Instructions for Use
14 No. PK0302260, a piece of vaginal mesh, and instruments
15 for use in implanting the mesh.

16 Is that fair, Doctor?

17 **A. That's fair.**

18 Q. Is this the product that you looked at in this
19 office?

20 **A. Yes.**

21 Q. Thank you. I am returning that to Mr. Potts.

22 Doctor, do you have any -- you were
23 describing your medical devices. They're very
24 interesting.

25 Have you had any -- do you have any

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1 degrees in engineering?

2 **A. No.**

3 Q. Have you had any other formal training in
4 engineering?

5 **A. No.**

6 Q. So you don't consider yourself to be any kind
7 of engineer, do you?

8 **A. I do not.**

9 Q. Have you had any other training on the
10 implantation or use of synthetic vaginal wall mesh, that
11 is other than the AMS training you attended?

12 **A. No.**

13 Q. Have you ever implanted a Bard Align product?

14 **A. No.**

15 Q. Have you ever implanted any Bard vaginal mesh
16 product?

17 **A. No.**

18 Q. Including biologics?

19 **A. No.**

20 Q. And, in fact, the only use of synthetic mesh in
21 a vaginal application is the abdominal sacrocolpopexy
22 procedure we discussed earlier?

23 **A. Right.**

24 Q. And I do have a little problem pronouncing
25 that.

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1 **A. Sacrocolpopexy. It -- it's a mouthful.**

2 Q. It is a mouthful.

3 Have you ever implanted -- strike that.

4 Have you ever explanted a
5 synthetic urethral sling?

6 **A. Yes.**

7 Q. About how many times have you explanted a
8 synthetic urethral sling?

9 **A. I am going to guess when I tell you this, but I**
10 **have done 75 to 100 explants of slings.**

11 I should also further characterize that
12 by saying in most instances that was done in concert
13 with removal of a device from the anterior vaginal wall.

14 Q. So that 75 to 100 just includes the slings,
15 right?

16 **A. The slings, plus devices from the anterior**
17 **vaginal wall.**

18 Q. Are there procedures that you've done when you
19 explanted anterior and posterior mesh --

20 **A. Yes.**

21 Q. -- separate and apart from the 75 to 100 you're
22 describing?

23 **A. Absolutely.**

24 Q. Okay. I am focusing mainly on the slings now.

25 **A. Okay.**

1 Q. When was the first time you did that, do you
2 think?

3 A. I am going to guess probably in 2008 or 2009.

4 Let me elaborate here and tell you that
5 our Pelvic Floor Center at Methodist, the Center for
6 Restorative Pelvic Medicine, became known in the city as
7 the place to go if you had a problem with mesh because
8 we did not have anybody on the staff who was in the
9 Center for Restorative Pelvic Medicine who at the time
10 was routinely using any synthetic mesh in the vagina.
11 We were mainly solving other people's mesh problems.
12 And we were taking it out; we were not putting it in.

13 And in many of these instances, if my
14 examination had indicated that this device was likely
15 going to involve the urethra or the bladder, then I
16 would work with a urologist, and we would be both
17 working together.

18 If I felt like there was a significant
19 chance that this mesh was going to involve the rectum,
20 then I would work with a colon rectal surgeon.

21 And that was the beauty of the center.
22 We were a very collaborative effort . And most of the
23 cases that I did as the Center Director were done in
24 concert with another specialist.

25 Q. Now, urethral slings were -- synthetic mesh

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1 urethral slings were produced in the mid-to-late
2 Nineties, correct?

3 **A. Correct.**

4 Q. And were you doing vaginal surgery before your
5 involvement with the Methodist Center?

6 **A. Oh, yeah.**

7 **I had been doing vaginal surgeries since**
8 **the day I went into practice, since 1976.**

9 Q. But the first time that you can recall that
10 you're estimating that you removed a synthetic mesh
11 vaginal mesh was 2008 or 2009; is that correct?

12 **A. That's my best guess.**

13 Q. When you remove a sling or treat a patient who
14 is complaining of something that might relate to a
15 sling, do you try to get ahold of the Operative Report
16 of when it was put in?

17 **A. If I can, yes.**

18 Q. So sometimes you can tell what product was
19 actually used, right?

20 **A. Did you say can, or cannot? I am sorry.**

21 Q. Sometimes you can tell, right?

22 **A. Sometimes you can know that, yes.**

23 Q. Do you recall explanting any Bard Align slings?

24 **A. Sure.**

25 Q. And about how many Bard Align slings have you

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1 explanted?

2 A. I don't know the answer to that. I can guess.

3 I can say that I have probably taken out
4 10 or 15 of them.

5 Q. And what is that estimate based on?

6 A. My recollection.

7 The other thing to realize here is that
8 in many instances the Urology Service would have seen
9 these patients first, and they would have me come in to
10 assist them taking out these devices, because in many
11 instances, it was going to involve a significant degree
12 of vaginal reconstruction. And most of the urologists
13 in the center were not comfortable doing a lot of that,
14 and they wanted a gynecologist involved in that part of
15 the operation.

16 So these would be -- and in many
17 instances, we would bill as co-surgeons. And there's a
18 specific CPT code that allows us to bill as co-surgeons
19 when we're doing these operative procedures, and I would
20 bill as a co-surgeon if I was working with a urologist
21 or a colon rectal surgeon.

22 Q. Of these 10 to 15 Bard Align slings that you
23 recall explanting -- that's out of the 75 to 100 slings
24 total -- the remainder were by other manufacturers,
25 correct?

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1 **A. Yes.**

2 Q. Did any one manufacturer stand out for you?

3 **A. No.**

4 Q. Have you ever authored a medical device warning
5 label, Doctor?

6 **A. No.**

7 Q. Have you ever reported an adverse event to the
8 FDA?

9 **A. I have not.**

10 Q. Have you ever sought or asked for a label
11 change for any medical device that you have prescribed
12 or used?

13 **A. I have not.**

14 Q. When you've given opinions as an expert before,
15 has -- have those opinions ever been challenged in court
16 as being inadmissible or unreliable?

17 **A. No.**

18 Q. Do you know if any of your opinions have ever
19 been excluded from the Court when offered?

20 **A. Not to my knowledge.**

21 Q. Do you consider yourself to be an expert on the
22 Bard Align products?

23 **A. I don't want to sound too much like**
24 **Bill Clinton here, but let me give you a nuance answer**
25 **to that: I am not an expert in material science. I am**

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1 not an engineer. I do not know what is involved
2 specifically in the manufacture of the Bard Align
3 product.

4 But I would venture to say that there
5 are -- there are probably not 100 people in the
6 United States right now who have read this stack of
7 articles dealing with these products, and there are
8 probably not another 100 people in the United States who
9 have my experience taking out mesh products.

10 I consider myself as a clinician an
11 expert in removal of vaginal mesh products.

12 Q. You have never implanted one, right?

13 A. I have not.

14 Q. Did you review the 510(k) submission that Bard
15 made to the FDA for the Align product?

16 A. I did not. I have not seen that.

17 Q. And do you know what the predicate devices
18 were?

19 A. Marlex and Protogen, which has been taken off
20 the market.

21 Q. So it's your opinion that the predicate device
22 for the Align mesh was the Marlex mesh and Protogen?

23 A. And Protogen, yes.

24 Marlex, in the general sense that it's a
25 polypropylene device.

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1 Q. And -- but you haven't ever reviewed the 510(k)
2 yourself, right?

3 A. I have not.

4 Q. And have you reviewed any of the information
5 that Bard submitted in that 510(k) in any other format?

6 A. I do not think so.

7 Q. And you've said you're not a material scientist
8 and not an engineer.

9 Is it fair to say that you're not an
10 expert in biomaterials or biomechanics?

11 A. I will say that I am not an expert in the
12 manufacturer and biomaterials and bioscience, yes.

13 I am an expert in taking it out, but I am
14 not an expert in manufacturing.

15 Q. I am asking more generally.

16 You agree that you're not an expert in
17 the field of material science, correct?

18 A. Yes.

19 Q. And you agree you're not an engineering expert,
20 right?

21 A. I am not an engineer.

22 Q. Have you ever yourself conducted any
23 biomaterial testing on synthetic mesh?

24 A. No.

25 Q. Have you ever had any education or training in

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1 the process that the FDA follows in approving or
2 clearing medical devices?

3 A. I -- when I was playing around with the
4 chemoluminescent products, I looked into that enough to
5 know that I didn't want to go there because of the cost
6 and the time that was going to be involved with getting
7 a product through the FDA. It's onerous, it's
8 expensive, it's time-consuming, and you don't know how
9 they're going to come down on it.

10 It's a gamble, and I didn't want to
11 gamble at this stage in my life.

12 Q. And for that, you consulted with a JD/MD,
13 correct?

14 A. Correct.

15 Q. So you're not an expert on FDA regulations, are
16 you?

17 A. I don't think so.

18 Q. Are you an expert on the process that the FDA
19 follows in clearing or approving medical device labels?

20 A. I think I am knowledgeable.

21 I don't think that I would call myself an
22 expert.

23 Q. Do you have any degree in epidemiology or
24 pathology?

25 A. No.

1 Q. Are you an expert in either of those areas?

2 A. No.

3 Q. Are you an expert in bacteria or infectious
4 diseases?

5 A. I would consider my knowledge of those fields
6 on a level playing with other OB/Gyns.

7 Q. Do you have any other formal training as a
8 specialist in infectious disease?

9 A. No.

10 Q. You're not a neurologist, correct?

11 A. Right.

12 Q. And you're not a pain specialist, right?

13 A. Right.

14 Q. Are you an expert in the design of medical
15 devices?

16 A. No.

17 Q. Have you ever done any testing on whether or
18 how synthetic mesh shrinks or contracts?

19 A. Did you say the word, "testing"?

20 Q. Yes, testing.

21 A. I have not.

22 Q. And have you done any testing on the tensile
23 strength of synthetic mesh?

24 A. No.

25 Q. Have you done any testing on the flexibility or

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1 elasticity of synthetic mesh?

2 **A. No.**

3 Q. Have you done any testing at all on the
4 properties of synthetic mesh?

5 **A. No.**

6 Q. Did you do any examination or testing of mesh
7 explanted from any of the seven plaintiffs on which you
8 are offering case-specific opinions?

9 **A. No.**

10 Q. Did you observe any of those explants, if they
11 exist?

12 **A. No.**

13 Q. Doctor, what did you do to prepare for today's
14 deposition?

15 **A. I read all of these articles.**

16 Q. Referring to the binder, correct?

17 **A. Referring to the binder.**

18 Q. Exhibit 11?

19 **A. Yes.**

20 **And I looked at this -- what did you call**
21 **the list?**

22 Q. The Reliance List?

23 **A. The Reliance List, yes.**

24 **I looked at the -- I scanned the**
25 **articles, and I spent a lot of time going over the**

1 reports that I have written so that I would be sure that
2 I was cognizant and familiar with them.

3 Q. Did you review any other documents?

4 A. I actually went to some chapters that I had
5 written for a textbook that I am an author of to see if
6 I had anything that I had put in writing previously that
7 was germane to this, and I did not find anything there.

8 But I did look at the textbook to make
9 sure that I wasn't going to say anything orally that I
10 hadn't put in writing.

11 Q. And what's the textbook?

12 A. Case Studies in Gynecologic Surgery. I am a
13 coauthor in that book. It's a McGraw-Hill publication.

14 Q. Did you speak with attorneys before today?

15 A. Yes.

16 Q. And who have you worked with? We've already
17 mentioned Mr. Potts.

18 A. Barfield.

19 Q. McBride?

20 A. Dan McBride is not an attorney. He's an
21 employee of the firm.

22 Q. Any other attorneys you've worked with before
23 today?

24 A. I need to ask Derek for Drew's last name.

25 MR. POTTS: Woellner.

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1 **A. Drew Woellner; I also spoke with him**
2 **previously.**

3 Q. (BY MR. BORANIAN) And did you meet with
4 attorneys before today?

5 **A. Yes.**

6 Q. When was the last time you met with an attorney
7 before today?

8 **A. One day last week.**

9 Q. And how long was that meeting?

10 **A. I think probably 45 minutes.**

11 Q. That was a face to face, right?

12 **A. Yes.**

13 Q. What did you discuss at that meeting?

14 **A. What to expect from defense counsel and how to**
15 **prepare for it and be nice and don't be aggressive and**
16 **all these kinds of things.**

17 Q. I appreciate that, Doctor.

18 Who was at that meeting?

19 **A. I think Mr. Potts was there, and I think**
20 **Mr. Barfield was there.**

21 Q. And what did they tell you about the
22 deposition?

23 What did they tell you to expect?

24 **A. He said to be asked questions about everything**
25 **you've put in writing, and he said to make sure you know**

1 **your stuff.**

2 Q. Did you review any of your opinions, generic or
3 specific?

4 A. **No.**

5 Q. Did you go through any sort of, you know, mock
6 examination or -- or practice questioning?

7 A. **No.**

8 Q. And before that, when was the last time you met
9 with attorneys about these cases?

10 A. **I would have to refer to my invoice. I don't**
11 **remember.**

12 Q. Okay. We will get to those.

13 A. **It will be -- I will promise you that my**
14 **billing technique is accurate and thorough, and I don't**
15 **miss anything. So it will be there.**

16 Q. Can you estimate how many times you've met with
17 attorneys to talk about this case -- these cases?

18 A. **Six or eight at the outside. It may be less**
19 **than that.**

20 Q. That's all on the invoices, right?

21 A. **Correct.**

22 Q. And we'll get to that.

23 A. **You will, yes.**

24 Q. Okay. Have you spoken with anyone else about
25 this deposition?

1 **A. My wife.**

2 Q. How about Dr. Gonzales?

3 **A. No.**

4 Q. Have you talked with any colleagues other than
5 Dr. Gonzales about your opinions in this case?

6 **A. No.**

7 Q. Have you spoken with Dr. Gonzales about your
8 opinions in this case?

9 **A. No.**

10 Q. Now, you have examined several of the
11 plaintiffs.

12 Those were face-to-face examinations,
13 right?

14 **A. Correct.**

15 Q. And you had the opportunity there to ask them
16 questions, right?

17 **A. Right.**

18 Q. Did any of them discuss the lawsuit with you,
19 their lawsuits with you?

20 **A. This was not anything that was done with**
21 **litigation in mind. I was functioning in the term -- in**
22 **the -- as a physician, and I wasn't there to ask them**
23 **anything about a lawsuit.**

24 Q. Okay. Well, the reason why it came about that
25 you examined them was because of the lawsuits, right?

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1 A. Oh, yeah.

2 I wouldn't have had occasion to see them
3 otherwise.

4 Q. Right. So litigation was on somebody's mind,
5 if not yours.

6 Did any of the plaintiffs mention it to
7 you, mention the lawsuits to you or talk to you about
8 the lawsuits?

9 A. Not that I recall.

10 Q. Now, if the patient was married, did you speak
11 with the husband?

12 A. I think that there may have been one husband
13 who was actually in the room talking with Gonzales and
14 the patient and me, but I don't recall that there were
15 more than one.

16 Q. Do you remember who that was?

17 A. I do not.

18 Q. Would that be in your report?

19 A. I doubt it.

20 Q. I don't recall seeing it.

21 A. I don't think that I specified that he was
22 there.

23 Q. Would it have been in your notes or
24 Dr. Gonzales' notes?

25 A. It could be in his.

1 I don't know what he put in his notes. I
2 didn't see that.

3 Q. Would it be in your notes?

4 A. No.

5 Q. Were you given any assumptions to use as a
6 basis for your opinion?

7 A. None.

8 Q. Were you given any additional facts or data to
9 review other than what's in Exhibit 11, the binder, or
10 on the Reliance List that's attached to your report?

11 A. No, sir.

12 Q. Doctor, what is stress urinary incontinence?

13 A. It is the involuntary loss of urine that
14 occurs -- I assume you're talking about women?

15 Q. Yes. In females, yes.

16 A. All right. If we can make that clear.

17 It occurs when the intraabdominal
18 pressure exceeds the capability of the urethra to keep
19 the urine in the bladder. It typically occurs to
20 laughing, sneezing, coughing, or straining.

21 There are two types: One is due to
22 urethra hypermobility, and the other is due to intrinsic
23 sphincteric deficiency. In other words, the
24 fibromuscular surroundings of the urethral munadis
25 [phonetic] are deficient, and the sphincter is not

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1 **working well. So those are the two reasons why women**
2 **lose urine.**

3 Q. Have you treated patients for stress urinary
4 incontinence?

5 **A. Absolutely.**

6 Q. And when did you first encounter a patient who
7 was complaining of stress urinary incontinence?

8 **A. In medical school.**

9 Q. And so have you treated women with that
10 condition throughout your career?

11 **A. Except for the two years I was in the Air Force**
12 **taking care of males.**

13 Q. Naturally.

14 There were no female pilots back then,
15 were there?

16 **A. No, there weren't.**

17 Q. So stress urinary incontinence is a significant
18 medical condition, right?

19 **A. It's a huge problem.**

20 Q. And do you agree that stress urinary
21 incontinence can affect a person's quality of life
22 significantly?

23 **A. I do.**

24 Q. Can it affect someone's self-esteem in a
25 negative way?

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1 **A. Yes.**

2 Q. Can it affect someone's sense of self-worth?

3 **A. Yes.**

4 Q. And have you observed that in patients you've
5 treated?

6 **A. Yes, yes.**

7 Q. Can stress urinary incontinence negatively a
8 person's sex life?

9 **A. Yes.**

10 Q. And you've seen that, as well, in your
11 practice, right?

12 **A. Yes.**

13 Q. Can stress urinary incontinence result in a
14 woman being homebound?

15 **A. It can.**

16 Q. And you've seen that in your practice, as well,
17 right?

18 **A. I have.**

19 Q. Now, have you ever seen any statistics for the
20 prevalence of stress urinary incontinence in females in
21 the U.S.?

22 **A. I have.**

23 Q. I have seen numbers that range from 30 to 50
24 percent.

25 **A. Those would be the exactly the numbers that I**

1 was going to quote back to you, Counselor. That's
2 correct.

3 Q. Okay. So this affects millions of women,
4 right?

5 A. Yes.

6 Q. What treatment options -- well, let me ask
7 first -- first, when physicians such as yourself are
8 faced with women complaining of medical conditions, in
9 this case stress urinary incontinence, you want to be
10 able to have different options to treat that patient,
11 correct?

12 A. Correct.

13 Q. Depending on his or her needs, correct, or her
14 needs?

15 A. Correct.

16 Let's stick with her.

17 Q. We'll stick with her.

18 A. Okay.

19 Q. What treatment options are available for women
20 with stress urinary incontinence?

21 A. An awful of women coming in using Depends or
22 wearing pads. That's not going to solve the problem,
23 but it's going to keep them dry in some instances or
24 dryer.

25 One of the things that I always recommend

1 to women if they're overweight is to lose weight,
2 because depending on which study you believe, 5 to 10
3 percent of women can improve their circumstance just by
4 taking off extra weight.

5 If you want to then get into more
6 specific medical therapies that a physician is likely to
7 be involved with, the first thing that we typically
8 suggest to women is pelvic floor physical therapy,
9 usually to involve Kegel exercises, and those have the
10 advantage of being noninvasive and relatively simple and
11 easy to do if taught correctly.

12 Women are notoriously unreliable in terms
13 of continuing with those, but it's been shown repeatedly
14 that they should be one of the first things that's
15 considered if you're trying to avoid surgery.

16 The next thing to be considered would be
17 a pessary, which is a device that is worn in the vagina
18 and which presses the urethra against the anterior
19 pelvis and occludes the flow of urine with the problems
20 that normally would provoke that.

21 There are coll -- there are coap-type
22 [phonetic] devices that can be injected around the
23 urethra, urethral bulking agents.

24 And finally, there are surgical
25 procedures.

1 Q. Are there any medications that you can
2 prescribe for stress urinary incontinence?

3 A. Only to the extent that it is involved with
4 mixed urinary incontinence, which is a combination of
5 urgency and stress incontinence.

6 By and large, medications don't work for
7 stress urinary incontinence.

8 Q. What are the surgical options that are
9 available today for stress urinary incontinence?

10 A. Historically, the operations that were used
11 were the Marshall Marchetti Krantz procedure and the
12 Burch procedure. Those involve a large abdominal wall
13 incision.

14 And while they were reasonably effective,
15 they've largely fallen out of favor because they involve
16 a major surgical procedure.

17 If a woman comes in with a cystocele,
18 which is a hernia in the anterior vaginal wall, when I
19 was in residency, I was taught that an anterior vaginal
20 wall repair or colporrhaphy using Kelly plication
21 sutures would be effective. As it turns out, that's not
22 very effective; probably 30 to 50 percent efficacy at
23 the most.

24 The sling procedures that came onto the
25 market revolutionized therapy -- excuse me -- for stress

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1 urinary incontinence, and I would say that the sling
2 procedures have become the mainstay operation for use
3 currently.

4 Q. They've become the standard of care, right?

5 A. They have.

6 MR. POTTS: Object to the form of the
7 question, vague and ambiguous as to, "standard of care."

8 Q. (BY MR. BORANIAN) And there are many
9 publications that are in your binder that refer to sling
10 procedure as the gold standard for the surgical
11 treatment of stress urinary incontinence, correct?

12 MR. POTTS: Same objection.

13 A. There are articles in the binder that call the
14 sling procedure the standard of care or gold standard.

15 Q. (BY MR. BORANIAN) What kinds of sling
16 procedures?

17 When you're talking about sling
18 procedures, what are you referring to?

19 A. Well, there's the tension-free vaginal tape.
20 There is -- that's a retropubic approach. There's also
21 a transobturator approach.

22 There are a lot of different approaches
23 going either through the lower abdomen or through the
24 groin, but they all have the basic concept of suspending
25 the urethra.

1 Q. So what you here describing are synthetic
2 slings, correct?

3 A. Correct.

4 There's also -- I should go back and
5 point out that I left out something that's significant
6 and can be used, and that's to use an autograft taking
7 the patient's own fascia either from the fascia lata on
8 the lateral aspect of the thigh or taking the patient's
9 fascia from the abdominal wall and using the patient's
10 own tissue to repair stress urinary incontinence.

11 Those are more major procedures because
12 you have to harvest the fascia, but they have the
13 distinct and significant advantage of being the
14 patient's own tissue that you're putting back into her.
15 She's not going to have any problems with rejecting her
16 own tissue.

17 Q. But that is a more involved procedure, right?

18 A. Yes.

19 Q. And it involves a larger incision than the
20 incisions that are required for the implantation of
21 urethral slings, right?

22 A. You have to harvest the tissue; that is true.

23 I have not seen any reports of people
24 harvesting the fascia with a laparoscope. I suspect
25 that those exist. I haven't specifically looked for

1 **that.**

2 And there are some tunneler devices that
3 are used from taking the fascia from the side of the
4 thigh which make it less invasive than making a large
5 incision.

6 But in general, to answer your question,
7 those are -- those involve another step in the process.

8 Q. So of the surgical procedures that you have
9 described, have you performed a Marshall Marchetti
10 procedure?

11 A. Back in residency.

12 Q. And that was in the mid 1970s, correct?

13 A. Correct.

14 Q. And have you performed a Burch procedure?

15 A. Back in the residency.

16 Q. So same time frame?

17 A. Same time frame.

18 Q. And you mentioned colporrhaphy?

19 A. "Colporrhaphy."

20 Q. As something that was once thought as indicated
21 for anterior repair, but that's not true?

22 A. Colporrhaphy and anterior, they are synonymous.

23 And colporrhaphy and anterior are
24 indicated when there is a cystocele, when there is a
25 hernia in the anterior vaginal wall. That is frequently

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1 associated with stress urinary incontinence.

2 Q. Okay. Got you.

3 A. What I am saying is that it's appropriate for
4 the gynecologist to repair the cystocele and doing that
5 would be an anterior colporrhaphy.

6 In hundreds of instances, I would do an
7 anterior colporrhaphy, but I would be working with a
8 urologist who was putting a sling in place.

9 Q. A synthetic sling?

10 A. Yes.

11 Q. Have you ever -- well, how many times have you
12 done that?

13 A. Hundreds.

14 Q. And in that case, you're not putting in the
15 sling; it's the urologist?

16 A. Correct.

17 And let me explain to you if I may here:
18 There are an awful lot of gynecologists who put in sling
19 procedures. My decision not to do that was as much
20 political and economic as it was anything else.

21 As the Director of the center, I wanted
22 to be sure that urologists would be comfortable
23 referring patients to the center. And they were not
24 going to send anybody to the center if they thought the
25 procedure that they were good at was going to be done by

1 somebody else.

2 So as a gynecologist, I didn't do any
3 procedures that I felt to be primarily urological in
4 nature. And likewise, I would have never sent a patient
5 of mine to a urologist if I thought that urologist was
6 going to do a vaginal hysterectomy. That was my bread
7 and butter, and I didn't want to send that to somebody
8 else.

9 I am not saying that there are not a lot
10 of gynecologists who can and do put slings in place.
11 But for economic and political reasons, I didn't have
12 occasion to do so.

13 Q. So you did it in tandem with urologists; is
14 that what you're saying?

15 A. Yes.

16 Q. So the hundreds of times you did that, you
17 thought that that combination of treatment was the best
18 option for each of those patients, right?

19 A. I did not make the decision for the urologist.
20 The urologist decided what he or she wanted to do for
21 the stress urinary incontinence.

22 My decision was to do a vaginal
23 hysterectomy if indicated, plus any repairs to the
24 vaginal apex or any repairs to the vaginal floor, a
25 posterior colporrhaphy. And I would do the anterior

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1 colporrhaphy.

2 The urologist would do his or her sling
3 procedure of choice, and they were using a lot of
4 different sling products. Some them were using a
5 MiniArc, Monarc. We -- they were using all kinds of
6 slings, and I didn't make that choice. That was the
7 urologist's choice.

8 Q. But those were polypropylene slings, right?

9 A. Yes.

10 Q. And you didn't express any reservation in any
11 of those cases contrary to the urologist's treatment
12 decision, did you?

13 A. It wasn't my call to make.

14 Q. You didn't express any reservations, did you?

15 A. No.

16 Q. How many times have you done an autograft
17 procedure?

18 A. Taking the fascia lata?

19 Q. Uh-huh, yeah.

20 A. Again, that was something I would defer to
21 Urology.

22 I have worked with urologists when they
23 were doing that, harvesting the fascia. But again, I
24 didn't do the procedure myself. That's why the
25 urologist was there.

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1 Q. Okay. I think I understand.

2 Well, you -- well, let me just ask you,
3 have you ever treated stress urinary incontinence with a
4 surgical procedure?

5 A. Early on in my career, before the data really
6 got good, I would try to treat this with an anterior
7 colporrhaphy. It didn't work very well. It was only 30
8 to 50 percent effective.

9 It would beautifully treat the cystocele,
10 but it wouldn't necessarily do anything for the stress
11 urinary incontinence.

12 Q. And when was the last time you did that?

13 A. Probably 2003 or 2004.

14 Q. So other than that, you really have not done
15 any surgical treatment for stress urinary incontinence,
16 right?

17 A. Correct.

18 Q. You leave that to the urologist?

19 A. Correct.

20 Q. So you have worked with and know physicians who
21 use synthetic mesh to treat stress urinary incontinence,
22 right?

23 A. Right.

24 Q. And you make your decisions, you consider and
25 weigh the risks and the benefits of each option, right?

1 A. If I was doing the operation, the answer to
2 that is yes.

3 I was not making those decisions for the
4 urologist. He or she was going to have to tell the
5 patient what they were going to use, and they were going
6 to have to go through that.

7 I didn't steal the urologist's thunder.
8 I wasn't doing that portion of the procedure, and I
9 wasn't going to cover any of that.

10 Q. Okay. On a more general level, though, each
11 patient's condition requires an individualized
12 assessment of the risks and benefits, right?

13 A. Right.

14 Q. And so what's right for one may not be right
15 for another patient; is that fair to say?

16 A. That's fair to say.

17 Q. Is it also fair to say that the decision to use
18 a particular treatment option depends in large part on
19 the surgeon's personal preference?

20 A. Yes.

21 Q. So some doctors prefer some procedures over
22 others, some products over others, things like that,
23 correct?

24 A. Correct.

25 Q. Would patient preference also play a part in

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1 making that decision?

2 A. I would say that I would be a fool not to
3 listen to a patient who came in with a request. I
4 wouldn't always honor that request if I felt like it
5 wasn't in the patient's best interest, and I would say
6 to her very candidly, "Mrs. Jones, you want me to do
7 something that I am not comfortable doing. I respect
8 your opinion, but I am not willing to do that to you. I
9 think you need to find another gynecologist."

10 Q. You're familiar with all of the television
11 advertisements about vaginal mesh, right?

12 A. I am not sure I am familiar with all of them.
13 I have seen several of them, yes.

14 Q. So has a patient ever come to you and said, "I
15 want my mesh explanted"?

16 A. Yes.

17 Q. Have you ever told the patient, "I have
18 assessed you. I have looked at your condition. In my
19 judgment, it should not need to be explanted"?

20 A. I have had occasion to tell them that, yes.

21 Q. And about on how many occasions have you
22 recommended that they stay the course?

23 A. Probably half a dozen; no more than that.

24 And it depends on what their symptoms
25 are. And I would -- if somebody comes in that's

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1 asymptomatic and doesn't have any visible problems at
2 all, and especially if her problem has been solved, if
3 she has no longer has stress urinary incontinence, then
4 I could not in good conscious tell her that she was
5 going to undergo another major surgical procedure just
6 because she had the mesh inside her.

7 Q. So what you're describing to us is a
8 risk/benefit analysis, right?

9 She's benefitting from the mesh sling
10 product, and the risk of another procedure isn't worth
11 it, right?

12 A. Based on current knowledge, I would that's
13 potentially true, yes.

14 Q. That's potentially true.

15 Well, you have made that treatment
16 recommendation for actual patients, right?

17 A. I have, but that's with the understanding that
18 when we're talking about mesh, permanent means
19 permanent.

20 And what's true about mesh in 2014 may
21 not be the whole truth that we're going to know 10 or 15
22 or 20 years from now. And it may be, as we learn more
23 about these devices, that they're going to be looked at
24 with increasing skepticism and concern about their
25 long-term safety. We simply don't know that right now.

1 And I will tell the patient, "Based on
2 what I see right now, I cannot see any good reason for
3 the mesh to come out. I reserve the right to change my
4 opinion as we get more information."

5 Q. So synthetic slings have been around since the
6 mid 1990s, right?

7 A. Right.

8 Q. So we're going on about 17, 18 years now of
9 experience with those devices?

10 A. Yes.

11 Q. Is it fair to say that we have long-term data
12 on the experience and outcomes with those devices?

13 A. We have about 17 years' worth, yes.

14 Q. We would always like to have more, wouldn't we?

15 A. Absolutely.

16 Q. 17 years is quite a lot for any medical device,
17 isn't it?

18 A. 17 years is 17 years. Res ipsa loquitur; it
19 speaks for itself.

20 I am not going to -- 17 years is
21 17 years. But I think this is an important thing to
22 keep in mind -- and this is one of the reasons why I was
23 never comfortable putting the product in -- if mesh is
24 put into a 40-year-old woman or a 35-year-old woman --
25 and I have seen that done -- she's not yet menopausal,

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1 and we don't know what's going to happen to that woman
2 after she stops making estrogen and after the vaginal
3 mucosa thins.

4 And we don't know what's going to happen
5 to that mesh after 20 years or after 25 years or after
6 30 years. So you can come back and ask me this question
7 when we have 30 and 35 years' worth of data.

8 I would say to you that 17 years is 17
9 years. That's not necessarily long-term data. It's 17
10 years' worth of data. That's better than having none at
11 all, but it is what it is. It's only 17 years' worth.

12 Q. Well, of the hundreds of times that you have,
13 with a urologist in tandem, done a hysterectomy followed
14 by a sling procedure, some of those patients were in
15 their 40s, right?

16 A. Yes.

17 Q. And you did not recommend to the urologist,
18 "Hey, don't do that. We don't know yet," did you?

19 A. No.

20 That's not my role. That's me saying as
21 a gynecologist that I know more about your urologic
22 product than you do. I have a healthy dose of ego, but
23 I am not that stupid.

24 Q. And you're referring to that other --

25 A. Of course.

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1 Q. And if doctors disagree on the proper treatment
2 for a particular patient, that doesn't necessarily mean
3 that either doctor is right or wrong, does it?

4 A. It does not. I would concur with that.

5 Q. Okay. So do you agree that the use of
6 synthetic mesh today remains a standard of care for the
7 surgical treatment for stress urinary incontinence?

8 MR. POTTS: Objection; vague, ambiguous,
9 calls for a legal conclusion.

10 THE WITNESS: Would you read that
11 question back to me, please, ma'am?

12 (Requested portion was read.)

13 MR. POTTS: Same objection.

14 A. I would say if I could change the word,
15 "synthetic mesh," to, "slings," then I would agree, but
16 I don't think that synthetic vaginal mesh is considered
17 in 2014 to be the gold standard for anterior
18 vaginal-wall prolapse.

19 If you're talking about slings
20 specifically, I will say to you that there's a body of
21 literature that suggests that slings are the standard of
22 care.

23 I am making a distinction here between
24 slings and synthetic vaginal mesh, if I may. That's the
25 distinction I am making to answer your question.

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1 Q. That's fine, Doctor. That's what I intended to
2 ask you, so we're on the same page there.

3 A. Okay.

4 Q. So I will ask you, do you agree that the use of
5 synthetic mesh slings remains a standard of care for the
6 surgical treatment for stress urinary incontinence?

7 MR. POTTS: Same objection.

8 He's already answered the question.

9 Asked and answered twice now.

10 A. If you'll take the synthetic vaginal mesh out
11 of it and just call it a sling, I will answer your
12 question in the affirmative.

13 Q. (BY MR. BORANIAN) Okay. I did say, "sling,"
14 for the record, so I think we're on the same page there.

15 Now, of the patients that you have seen
16 treated with synthetic vaginal slings, the hundreds of
17 patients -- when we say, "hundreds," how many do you
18 mean?

19 Is more than 200?

20 A. No.

21 I would say it's probably around 150 to
22 200.

23 Q. You have also treated those patients, correct?

24 A. Yes.

25 Q. And so you've also been involved in the

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1 follow-up care for those patients, true?

2 A. Yes.

3 Q. So were you receiving -- have you received good
4 outcomes in those patients with the use of synthetic
5 slings to treat stress incontinence?

6 A. Let's make a distinction here, if I may.

7 The patients who came in to me to have
8 the slings removed did not have good outcomes. You're
9 not asking about that subset of patients.

10 If you're asking me about patients who I
11 have seen in followup who didn't have any problems,
12 then, yes, I have a significant number of patients that
13 I saw routinely that I operated on with Urology who had
14 successful results from slings.

15 Q. That's what I am asking.

16 A. Then the answer is yes.

17 Q. So of that group of patients, those that you
18 have treated in conjunction with the urologist, did you
19 see any complications in that patient population with
20 the synthetic slings?

21 A. Sure I saw complications.

22 But when there were no complications,
23 they were happy campers. When there were complications,
24 they weren't very happy, and some of those patients had
25 to be explanted and/or have sling revisions.

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1 Q. Some of the patients that you treated?

2 A. Yes.

3 Q. Okay. Just so we're clear on that, do you know
4 if any of the patients that you treated in conjunction
5 with urologists had a Bard Align sling implanted?

6 A. Yes.

7 Q. Do you know how many?

8 A. No.

9 Q. Is it -- can you estimate by proportion?

10 Is it less than half?

11 A. Oh, it's less than half.

12 I would say probably 10 to 15 percent, my
13 best guess.

14 Q. Have you -- in patients that you have treated
15 where you participated in the implantation of the mesh,
16 the sling, did you ever see a complication in someone
17 who had a Bard Align sling implanted?

18 A. Where I participated?

19 Q. Yes.

20 A. Yeah.

21 Q. And how many times did you see a complication
22 from the Bard Align sling?

23 A. I don't remember.

24 Q. Is it more than -- more than once?

25 A. Sure.

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1 Q. Is it more than five times?

2 A. Probably.

3 I wouldn't say it's any more than that.

4 Q. So -- so in the hundreds of patients -- 150 to
5 200 patients to be precise --

6 A. Yeah.

7 Q. -- perhaps 5 of those patients experienced a
8 complication with the Bard Align System; is that fair to
9 say?

10 A. To the best of my recollection.

11 Q. And what kinds of complications did you observe
12 in those patients?

13 A. Erosion, dyspareunia, chronic pelvic pain. We
14 had one instance where the device eroded into the
15 urethra and had to be explanted for that reason.

16 Q. So we had the one explant.

17 Were there any other explants in that
18 group?

19 A. Yes.

20 As I said, I probably have been involved
21 in taking out ten of these. I don't remember the
22 reasons we had to do it.

23 And in many instances, they would come
24 back in, and they didn't always see me for the
25 urological complications. I got involved if there was a

1 gynecologic aspect.

2 There were an awful lot of instances
3 where slings would be too tight, and the patient would
4 go into urinary retention and could not urinate. In
5 some instances, the urologist would have to go in and
6 cut the device, and the patient would then become
7 incontinent of urine again.

8 Q. When you cut the device, you just release it on
9 both sides, right?

10 You don't take it out?

11 A. No. You don't -- the first attempt would be
12 just to cut it.

13 If it was not a pain problem, if she was
14 in urinary retention, and all the things that the
15 urologist or I could do in the office had been done,
16 then we would simply open up the vaginal mucosa and make
17 an incision and cut the sling in half with the
18 understanding that the patient would be likely to
19 experience urinary incontinence again because the device
20 had been cut.

21 Q. And you're referring now to all the patients
22 that you have seen, right?

23 A. Yes.

24 Q. Okay. So I -- I am trying to understand, the
25 patients where you participated in the procedures that

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1 resulted in the implantation of a Bard Align mesh, you
2 said maybe five returned with complications?

3 A. Yeah.

4 Q. I think you said -- you identified one where
5 there was an erosion, and that required explantation.

6 Were there any other explants in that
7 group of five that you can recall?

8 A. There were others. I don't recall why.

9 But that's -- and that number, five, is
10 my best guess. I -- I don't have a list saying I took
11 out Device A, Device B. I don't remember that.

12 Q. I understand that.

13 We'll -- were all five of them explants;
14 do you remember that?

15 A. Yes.

16 Q. Okay. So of that group, when you identify
17 those five cases, those all had complications requiring
18 an explant of the mesh?

19 A. Yes.

20 Q. So when you say, "explant," do you mean the
21 whole mesh or just the stitching?

22 What do you mean?

23 A. No.

24 If we say, "explant," to me, that means
25 you're attempting to take it out.

1 Now, in -- if you'll look at -- may I see
2 this thing right here?

3 If you're looking at this piece of tape,
4 you've only got this much of it (indicating) that you
5 can easily get to through the vagina. And what happens
6 with the tape from here to here, you can't begin to get
7 that out once it's put in place.

8 So when you're taking mesh out, you're
9 only taking out -- you cut it here and you put an Allis
10 clamp on one side and you put an Allis clamp on the
11 other. And you try to trace it back as far as you can
12 going up into the hinterlands, but you can't begin to
13 get this stuff out once it's been in place for a year.

14 Q. So you're describing the 3 to 4 centimeters
15 that actually rest beneath the urethra, correct?

16 A. Correct.

17 Q. And that's beneath the urethra and above the
18 vagina, right?

19 A. Correct.

20 Q. And when you try to take them out, the way
21 other doctors describe them to me is you sort of track
22 up the arm for as long as you can.

23 Is that what you do, Doctor?

24 A. Yes.

25 Q. And when's the last time you did that?

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1 **A. 2014.**

2 Q. Okay.

3 **A. I mean 2013 -- I am sorry -- last year.**

4 Q. And -- okay. Let's move on.

5 Do -- so there are urologists at your
6 center, your -- the Methodist Center that use surgical
7 mesh to treat stress urinary incontinence?

8 **A. There are.**

9 Q. And are there urogynecologists at the
10 Methodist Center who use synthetic slings to treat
11 stress urinary incontinence?

12 **A. Yes.**

13 Q. Have they ever told you what kinds of results
14 they are getting with those products?

15 **A. Specifically, no.**

16 Q. Are they getting good results with those
17 products?

18 **A. I would say yes.**

19 Q. Is it fair to say that millions of women have
20 been successfully treated with synthetic mesh slings
21 with stress urinary incontinence?

22 **A. I don't know the answer to that question.**

23 If you were to say hundreds of thousands,
24 I would probably be more comfortable agreeing with you.
25 I don't know if millions of women have been treated with

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1 with slings or not. I don't have any idea what the
2 company's sales are or how many of these things have
3 been implanted.

4 How about if I say there have been a
5 bunch of them?

6 Q. Okay. I will take hundreds of thousands,
7 Doctor.

8 A. Okay. All right.

9 Q. Are you familiar with the AUGS' statement on
10 the use of slings?

11 A. I have seen it. Yes.

12 Q. You are a member of AUGS, right?

13 A. I am.

14 Q. Let's take a look at this, Doctor. This is
15 Exhibit No. 12.

16 (Reeves Exhibit No. 12 was marked.)

17 Q. (BY MR. BORANIAN) And, Doctor, this is
18 prepared jointly with --

19 A. SUFU.

20 Q. -- SUFU, The Society of Urodynamics Female
21 Pelvic Medicine and Urogenital Reconstruction.

22 Is that right, Doctor?

23 A. That is right.

24 Q. And what is SUFU?

25 A. SUFU is an -- it's not as big as AUGS, and this

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1 is primarily -- and I have never been to a SUFU meeting.

2 I have got colleagues that do go to SUFU.

3 I think that there are probably a lot
4 more urologists in SUFU than there are gynecologists,
5 but I am not sure about that. But it is another
6 professional organization whose membership has as its
7 focus of interest what they describe in their title.

8 Q. And you're not only a member of AUGS, but an
9 active participant?

10 A. Correct.

11 Q. And you presented there just recently?

12 A. As I said, I didn't present.

13 The paper that I was a senior author of
14 was presented at that meeting.

15 Q. You did say that, Doctor. You are right.

16 So it's an organization whose opinions
17 you look to and trust, right?

18 A. I look to them, and I listen to them.

19 I don't always agree with them.

20 Q. And doctors don't always agree -- well,
21 nobody -- professionals don't always agree with
22 everything that the professional organizations say, do
23 they?

24 A. They do not.

25 Q. But generally speaking, AUGS is a

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1 highly-reputable organization, right?

2 MR. POTTS: Objection.

3 A. I wouldn't belong if I didn't think it were.

4 Q. (BY MR. BORANIAN) Okay. So if you look at the
5 introduction on Exhibit 12, it says that the purpose of
6 this Physician Statement by the American Urogynecologic
7 Society and the Society of Urodynamics Female Pelvic
8 Medicine and Urogenital Construction is to support the
9 use of a midurethral sling in the surgical management of
10 stress urinary incontinence.

11 That's AUGS' position, correct?

12 A. They say that's the purpose of this position,
13 yes.

14 Q. AUGS supports the use of urethral slings in the
15 management of stress urinary incontinence, correct?

16 A. Correct.

17 Q. Do you support the use of the midurethral sling
18 in surgical management of stress urinary incontinence?

19 A. In some instances.

20 Q. And there are several doctors at the
21 Methodist Center who use the midurethral sling in the
22 surgical management of stress urinary incontinence,
23 right?

24 A. Right.

25 Q. It says here at the very bottom of the page --

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1 well, I should say for the record, this Exhibit 12 is
2 the AUGS' Physician Statement on mesh midurethral slings
3 for stress urinary incontinence. It goes on to say,
4 "Polypropylene mesh midurethral sling is a recognized
5 worldwide standard of care for the surgical treatment of
6 stress urinary incontinence. The procedure is safe,
7 comma, effective, comma, and has improved the quality of
8 life for millions of women."

9 Did I read that correctly, Doctor?

10 A. You read it correctly.

11 Q. Do you agree with that, sir?

12 A. Parts of it.

13 Q. Which parts do you agree with?

14 A. I am not sure that we have adequately
15 demonstrated the safety of these products. I think it's
16 effective.

17 I think -- and I have to tell you
18 something: When I got involved in looking at the
19 case-specific problems, I had no idea that as many women
20 were having problems with slings as were having problems
21 with them, and I have come to see this from an entirely
22 different perspective.

23 I will tell you that if you had asked me
24 these questions a year ago before I had a chance to see
25 some of the specific problems that have occurred, I

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1 would have said, "I support the AUGS' position 100
2 percent."

3 That's no longer the case.

4 Q. Well, what have you seen in the last year that
5 you hadn't seen before?

6 Doctor, you have been treating women and
7 explanting surgical mesh since 2008 to 2009.

8 A. Uh-huh.

9 Q. So you have seen women with complications
10 from --

11 A. And I didn't --

12 Q. Let me finish.

13 A. Sure. I am sorry.

14 Q. You have seen in your practice women by the
15 hundreds with complications from the implantation of
16 some form of surgical mesh, correct?

17 A. Correct.

18 Q. So why a year ago has your opinion tempered on
19 whether or not the procedure is -- is appropriate?

20 A. I said safe, not appropriate.

21 I think the biggest thing that I have
22 seen is the specific number of sling cases that have
23 been problematic.

24 Most of the problems that I have seen
25 prior to getting involved in this have been with the

1 vaginal mesh products, not the slings. I hadn't been
2 aware of the fact until about a year ago -- eight or ten
3 months ago that there was as many problems as there had
4 been with the slings.

5 And then when I would take these women
6 back into the operating room with the urologists --
7 excuse me -- some of the times, the slings were in good
8 position. And others, they had moved. And it was
9 necessary to take out the sling.

10 And it's difficult if you've got both
11 devices, because they can be so close together, to know
12 which is causing the problem. Is it the sling, or is it
13 the vaginal mesh that's supporting the anterior vaginal
14 wall?

15 Q. So you have seen seven individual patients,
16 right?

17 A. Yes.

18 Q. And most of them had a sling implanted, not
19 all, right?

20 A. I would have to look at them individually to
21 answer that question.

22 Q. Okay. I will represent to you that most, but
23 not all, had a sling implanted.

24 Other than that number of patients, what
25 have you learned about complications with vaginal --

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1 with synthetic mesh slings that you didn't know before?

2 A. I have become much more knowledgeable as a
3 result of all of the reading that I have done about the
4 fact that something that I thought, and I think a lot of
5 physicians thought, was a pretty inert product, i.e.
6 polypropylene, is not inert at all. And I have really
7 become educated about that to the extent I haven't
8 previously.

9 I think physicians are pretty naive in
10 what they sometimes accept as truth from medical device
11 manufacturers, and I don't think that that has been
12 something that I was aware of as much as I am now.

13 Q. So it's the -- it's the material that you
14 reviewed as a result of being retained as an expert in
15 these cases, correct?

16 A. Correct.

17 Q. So it's the litigation materials that you have
18 reviewed that have formed your opinions, right?

19 A. I am going to say to you that these are not
20 litigation materials. These are articles from respected
21 medical journals.

22 I had no idea about the extent to which
23 polypropylene undergoes degradation once it's been put
24 into the body.

25 The other thing that was a huge eye

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1 opener to me was the extent to which Bard had engaged in
2 what I am going to call subterfuge in putting these
3 devices on the markets.

4 What they bought from Chevron Phillips
5 Sumika, if that's the name of the company, has
6 essentially a Black Box Warning on it that says, "This
7 product is not designed for use inside the human body."

8 And Bard create a shell corporate entity
9 to buy that polypropylene from Chevron Phillips Sumika
10 through what they named Red Oak so that Chevron Phillips
11 wouldn't know it was being put into the body.

12 Q. So you're drawing inferences about Bard Align's
13 conduct and its motives and its intent based on your
14 review of those documents produced in discovery,
15 correct?

16 MR. POTTS: Object to the form of the
17 question.

18 A. I am.

19 Q. (BY MR. BORANIAN) Why don't you turn to the
20 second page of the AUGS' statement, Doctor?

21 A. Okay.

22 Q. The first thing it says is, number one,
23 "Polypropylene material is safe and effective in
24 surgical implant."

25 It says, "Polypropylene material has been

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1 used in most surgical specialties including general
2 surgery, cardiovascular surgery, transplant surgery,
3 ophthalmology, otolaryngology, gynecology, and urology for
4 over five decades in millions of patients in the U.S.
5 and in the world."

6 **A. Is there a question?**

7 Q. Did I read it correctly, Doctor?

8 **A. You got it all right. My hats off to you.**

9 Q. Doctor, it's true that polypropylene material
10 has been used in implants for 50 years, isn't it?

11 **A. It is.**

12 Q. And it's been used in mesh slings for about
13 17 years, right?

14 **A. Yes.**

15 What I cannot tell you, because I don't
16 know, is what grade polypropylene manufacturers other
17 than Bard have used in these other disciplines. I am
18 not an ophthalmologist, I am not a cardiovascular
19 surgeon, and I don't know if there was a warning on the
20 products that were used by these other surgical
21 specialties that said expressly, "This should not be
22 placed in the human body."

23 Q. So are you aware of different grades of
24 polypropylene?

25 **A. There is medical-grade polypropylene, yes, and**

1 then there is what Phillips Sumika said, "Don't put in
2 the body."

3 And they did not for whatever reason --
4 and I am going to leave that to the manufacturer. They
5 did not want their polypropylene implanted in the human
6 body.

7 Q. And upon what do you base your opinion that
8 there is medical-grade polypropylene as opposed to other
9 grades of polypropylene?

10 A. I have seen it referenced in some of these
11 articles.

12 Q. So --

13 A. I don't have any expertise in polypropylene
14 manufacture; we've established that already, okay?

15 Q. You do not know the formulation or grade of
16 various kinds of polypropylene, right?

17 A. I do not.

18 Q. So you're basing that opinion solely on the
19 documents you've reviewed in this case, right?

20 A. Correct.

21 Q. Including the documents produced in discovery,
22 right?

23 A. Correct.

24 Q. The second thing that the AUGS' statement says
25 is, "The monofilament polypropylene mesh MUS is the most

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1 extensively-studied anti-incontinence procedure in
2 history."

3 And you agree, Doctor, that there is a
4 substantial body of literature supporting the use of
5 midurethral slings, including those made of
6 polypropylene, correct?

7 **A. Correct.**

8 Q. It says, going on, "A broad evidence base,
9 including high-quality scientific papers in medical
10 journals in the U.S. and the World support the use of
11 the MUS as a treatment for SUI. There are greater than
12 2,000 publications in the scientific literature
13 describing the MUS in the treatment of SUI. These
14 include the highest level of scientific evidence in the
15 peer-reviewed scientific literature."

16 Is that what it says, Doctor?

17 **A. You read it correctly.**

18 Q. Do you agree with that, Doctor?

19 MR. POTTS: Objection; extremely overly
20 broad, compound.

21 You're asking him to agree with the whole
22 paper?

23 MR. BORANIAN: With what I just read.

24 Q. (BY MR. BORANIAN) Do you agree with that?

25 **A. Let's take it sentence by sentence.**

1 There have been a lot of papers written;
2 I'll agree with that.

3 There are greater than 2,000
4 publications; I will agree with that.

5 These studies include the highest level
6 of scientific evidence in the peer-reviewed literature;
7 there are good papers. There are not so good papers.
8 But the preponderance of opinion according to this AUGS'
9 statement indicates that AUGS is firmly behind the
10 concept of using the midurethral sling. They consider
11 it to be safe and efficacious.

12 Q. (BY MR. BORANIAN) And is that your opinion, as
13 well?

14 A. Not entirely.

15 And I am concerned about what I have seen
16 as a result of my involvement with these cases,
17 specifically regarding the safety -- the long-term
18 safety of a permanent product, polypropylene, placed in
19 the body, because it is truly not inert.

20 That has been a -- I could almost word
21 for word say the same thing about polypropylene, saying
22 there's a significant body of evidence that indicates
23 that this is not an inert product, and we cannot with
24 certainty say that this is a safe product because we
25 don't have enough -- we have 17 years' worth of data in

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1 the pelvis with the slings. We don't have any more than
2 that.

3 THE VIDEOGRAPHER: I need to change
4 tapes.

5 MR. BORANIAN: Okay.

6 THE VIDEOGRAPHER: We are off the record.
7 The time is 12:30.

8 (Lunch recess from 12:30 p.m. to
9 1:05 p.m.)

10 THE VIDEOGRAPHER: We are back on the
11 record. The time is 1:05 p.m.

12 Q. (BY MR. BORANIAN) Doctor, we were talking
13 about the AUGS' data before we broke for lunch, and the
14 AUGS' data makes reference to the FDA's opinions on
15 midurethral slings.

16 I think you have the FDA's Physician
17 Statement there in front you, but I will give you a copy
18 marked as an exhibit.

19 (Reeves Exhibit No. 13 was marked.)

20 Q. (BY MR. BORANIAN) This is Exhibit 13.

21 A. I have got one that's identical. I will let
22 you keep that.

23 Q. Okay. We'll let the court reporter keep the
24 one that's marked.

25 A. All right.

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1 Q. So this is a document called, "Considerations
2 of Surgical Mesh for SUI."

3 Is that right, Doctor?

4 A. That's right.

5 Q. And when I checked last, this was still up a
6 few days ago up on the FDA's Web site.

7 It says here at the beginning, "Mesh
8 sling procedures are currently the most common type of
9 surgery performed to correct SUI. Based on industry
10 estimates, there are -- there were approximately 250,000
11 of these procedures performed in 2010."

12 Do you have any reason to disagree with
13 that statement, Doctor?

14 A. No.

15 Q. "While all surgeries for SUI carries some risk,
16 it's important for you to understand the unique risks
17 and benefits and risks for surgical mesh slings used in
18 SUI repair."

19 That's what the document says, right?

20 A. That's what it says, correct.

21 Q. And FDA is the Government body for regulated
22 medical devices, right?

23 A. Yes.

24 Q. And they went through a review of
25 Adverse Event Reports resulting in a statement published

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1 in 2008, correct?

2 **A. Correct.**

3 Q. And another one published in 2013, correct?

4 **A. Correct.**

5 Q. This one is the current statement, at least
6 when it comes to SUI. And the first bullet point says,
7 "The safety and effectiveness of multi-incision slings
8 is well-established in clinical trials that follow
9 patients for up to one year."

10 You agree with that, right?

11 **A. That's what it says.**

12 Q. You agree with that statement, correct?

13 **A. For patients followed up to one year, that's**
14 **correct.**

15 Q. And it says, "Longer follow-up data is
16 available from the literature, but there are fewer of
17 the long-term studies compared to studies with one-year
18 followup."

19 You would agree with that, correct?

20 **A. I would agree with that.**

21 Q. And that's -- from what I understand, that is
22 the kernel of your opinion that it's the long-term data
23 you want to see, right?

24 **A. Yes.**

25 Q. And FDA has done a review, and FDA has said

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1 that there's longer follow-up data available in the
2 literature, right?

3 A. That's what they say.

4 Q. And you agree with that?

5 A. The -- the information is in the literature.

6 Again, we -- the -- the only information
7 that we have about long-term -- about safety is based on
8 the one-year followup. We don't have a lot more
9 long-term data, and that's what I am asking for more of.

10 You know, as I told you much earlier
11 today, one of the big reasons that I was never big on
12 using these products -- and this has not changed since
13 the get-go.

14 You have asked me how many vaginal mesh
15 procedures I have done using synthetic procedure. And
16 my answer, with the exception of abdominal sacral
17 colpopexy, was an honest zero, because there was no
18 prospective long-term clinical trials showing this was
19 safe and efficacious.

20 Q. But the FDA's position is that the devices are
21 safe and effective, right?

22 MR. POTTS: Objection; form.

23 A. That's the position the FDA has taken.

24 Q. (BY MR. BORANIAN) And you described a case
25 report that you published on rectal erosion. This is

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1 Exhibit 14.

2 (Reeves Exhibit No. 14 was marked.)

3 Q. (BY MR. BORANIAN) This is Exhibit 14, Doctor.

4 This is the Case Report that you
5 described, is it?

6 A. That is correct.

7 Q. And this is a Case Report of rectal erosion of
8 synthetic mesh used in posterior colporrhaphy?

9 A. "Colporrhaphy," if you don't mind me correcting
10 you.

11 Q. I don't mind at all.

12 A. Okay.

13 Q. I will do it again; trust me.

14 A. All right.

15 Q. So this is not, again, a Case Report involving
16 a synthetic mesh sling, correct?

17 A. Correct.

18 Q. And in the introduction, in the middle of the
19 introduction, you write, "Polypropylene mesh has been
20 widely used and studied in such procedures as abdominal
21 sacral colporrhaphies and numerous midurethral slings."

22 That's what you wrote in 2007 when you
23 and your coauthors published this Case Report, correct?

24 A. That's correct.

25 Q. Now, you have expressed some reservations in

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1 the Case Report about the use of vaginal mesh for organ
2 prolapse, correct?

3 **A. Correct.**

4 Q. But when it came to midurethral slings, your
5 position in 2007 was that they had been widely used and
6 studied, right?

7 MR. POTTS: Objection; misconstrues the
8 evidence.

9 **A. I said -- to quote from the paper,**
10 **"Polypropylene mesh has been widely used and studied in**
11 **such procedures as abdominal sacral colpopexies and**
12 **numerous midurethral slings."**

13 Q. You said that in 2007, correct?

14 **A. Correct.**

15 Q. And you believed that when you said it,
16 correct?

17 **A. That's fact, yeah.**

18 **I didn't say anything about its safety; I**
19 **just said it's been used and studied.**

20 Q. Now, you mentioned the -- the warning that came
21 with the polypropylene resin?

22 **A. Yes.**

23 Q. And that's the Material Safety Data Sheet,
24 right?

25 **A. Correct.**

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1 Q. So let's go to your report, Doctor, Exhibit 2.

2 If you go to page 5 of your report --

3 A. I am there.

4 Q. -- this is where you begin to lay out your
5 expert opinions, correct?

6 A. Correct.

7 Q. Doctor, under letter A, is that an accurate
8 reflection of the first opinion you hold in these cases?

9 A. Yes.

10 Q. And that opinion is that Bard's Align mesh is
11 not suitable for its intended application as a permanent
12 prosthetic implant for SUI in the human body and is
13 defective and unreasonably dangerous because the
14 manufacturer of the raw polypropylene resin has clearly
15 warned that it should not be placed inside the human
16 body.

17 That's what it says, right?

18 A. That is what it says.

19 Q. And that is your opinion?

20 A. That is my opinion.

21 Q. And that is based on the
22 Medical Application Caution that you quote on page 6; is
23 that right, Doctor?

24 A. Yes.

25 Q. You understand that that Medical Application

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1 Caution was printed in something called a
2 Material Safety Data Sheet, right?

3 **A. I understand exactly what those are.**

4 Q. Or an MSDS, right?

5 **A. Yes.**

6 Q. Now, you've already established that
7 polypropylene has been implanted permanently in humans
8 for over 50 years, right?

9 **A. Right.**

10 Q. Before you were hired by the plaintiffs in this
11 case, had you ever reviewed a Material Safety Data Sheet
12 for the materials used in the devices that you use?

13 **A. Yeah.**

14 Q. When?

15 When was that?

16 **A. When I would use something new and different,**
17 **for instance suture devices, I would always make sure**
18 **that I looked at that.**

19 And the other thing to keep in mind --
20 and I don't know if you're aware of this or not. But
21 when I was in private practice, we had to have a folder,
22 not unlike these black binders I have got here today,
23 that had a Material Safety Data Sheet in it for every
24 chemical product that we had in the medical office.

25 So I have seen these things, and we had

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1 to keep those things up to date. We had to check them
2 annually. And if I had a bottle of isopropyl alcohol in
3 the office, I had to have the Material Safety Data Sheet
4 on hand for that bottle of isopropyl alcohol.

5 I am familiar with those.

6 Q. Sorry.

7 A. Go ahead.

8 Q. So you were -- you were running a workplace,
9 correct?

10 A. Sure.

11 Q. And so you agree that the purpose of an -- of
12 an MSDS is to ensure that information concerning a
13 chemical's potential hazards are communicated to an
14 employee and others that work in the workplace, right?

15 MR. POTTS: Objection; form, calls for a
16 legal conclusion.

17 A. I think it's probably there to protect the
18 employees, yes.

19 Q. (BY MR. BORANIAN) And Material Safety Data
20 Sheets are regulated by the
21 Occupational Safety & Health Administration, right?

22 A. I am assuming you know the answer to that
23 question, and it's probably yes.

24 I don't -- I think it was an -- OSHA is
25 the regulating Governmental agency.

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1 Q. And OSHA regulates safe and healthy workplaces,
2 right?

3 A. Right.

4 Q. And OSHA doesn't regulate medical devices,
5 right?

6 A. To the best of my knowledge, they do not.

7 Q. That's the FDA's bailiwick, right?

8 A. Correct.

9 Q. So would you agree that the dangers that a
10 worker faces when handling raw materials in the
11 workplace are different from dangers that might be
12 presented in the use of a finished product by the end
13 user?

14 MR. POTTS: Objection, overbroad, vague,
15 ambiguous.

16 A. Repeat that for me, if you would, please?

17 Q. (BY MR. BORANIAN) Do you agree that the
18 dangers that workers may face when processing raw
19 materials are different from the dangers presented in
20 the use of a finished product by end users?

21 A. Yeah, those can be different; I would agree
22 with that.

23 Q. Because the MSDS deals with the raw
24 polypropylene resin, correct?

25 A. My impression is, is that that deals with the

1 finished product. That deals with the polypropylene,
2 and it's not in resin form.

3 They've already got -- this is a bulk
4 clump of polypropylene and it's got to be extruded into
5 the fibers and filaments, but it's not going to have the
6 chemical nature of the substance changed as a result of
7 taking raw polypropylene and making it into mesh.

8 Q. So it's taken from the raw polypropylene state,
9 and it's extruded into a fiber, correct?

10 A. I think that's correct.

11 Q. And that fiber is then woven into a mesh,
12 correct?

13 A. Correct.

14 Q. And then that mesh is formed, in the case of
15 the Align mesh, into a precut medical device, right?

16 A. Correct.

17 Q. And it's sterilized and packaged in the way
18 device manufacturers do, right?

19 A. Right.

20 Q. And it's further handled by the surgical staff
21 when it's placed inside of a patient, right?

22 A. Right.

23 Q. So there's multiple steps from the raw
24 polypropylene resin to implantation into the patient,
25 right?

1 A. Right.

2 But I am going to qualify that by saying
3 that I don't think that this product that I am holding
4 in my hands right now, the finished product, is
5 significantly different from a chemical construction and
6 chemical make-up standpoint than it was when it was in
7 its raw-resin state as sold by Chevron Phillips Sumika.

8 I am saying polypropylene is
9 polypropylene, as it relates to the manufacture of the
10 Align product.

11 Q. And you've already told us that you're not an
12 expert in polymer sciences, right?

13 A. Correct.

14 Q. And you're not an expert in the manufacture of
15 these devices, right?

16 A. That's right, but that doesn't negate what I
17 just told you about this product.

18 Q. Well, I am trying to establish your expertise,
19 Doctor.

20 And you are a medical doctor, right?

21 A. Right.

22 Q. And you have reviewed medical literature in
23 connection with this case, right?

24 A. Right.

25 Q. You have a whole binder sitting in front of

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1 you, right?

2 A. Right.

3 Q. Have any of those articles cited a
4 Material Safety Data Sheet in connection with the
5 medical or scientific study they've done?

6 A. I don't think so.

7 Q. Can you think of a -- of any articles that you
8 have reviewed over your career that have referred to or
9 cited the Material Safety Data Sheet for a raw material
10 when discussing a medical device?

11 A. Probably not.

12 But the other -- the other point that I
13 want to make here is the fact that I haven't seen them
14 doesn't mean they don't exist, obviously. And I have
15 never seen anything like the one for the polypropylene
16 product that says do not use this material in the human
17 body.

18 In fact, I would venture to say that if
19 you were to show that particular paragraph to a thousand
20 urologists who were implanting this device in the human
21 body, that 995 of them would refuse to use it if the
22 manufacturer said, "This is not safe to use in the
23 body."

24 Physicians are simply not aware of this
25 warning. It says, "Don't use it. It's not safe."

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1 Q. Because physicians relied in part on the advice
2 of their peers, right?

3 A. Of course.

4 Q. And physicians rely in part on the advice and
5 thoughts of the professional organizations that they
6 belong to, right?

7 A. They certainly take those into account.

8 Q. And physicians also rely in part on the FDA's
9 review of safety and efficacy, right?

10 A. To some extent.

11 We don't have a lot of respect for the
12 FDA; I have got to tell you that.

13 Q. And the FDA is aware of this
14 Material Safety Data Sheet, right?

15 MR. POTTS: Objection; calls for
16 speculation.

17 A. I don't have any idea if the FDA was aware of
18 this or not. I am not in a position to answer that
19 question.

20 I will tell you that Chevron -- that Bard
21 bent over backwards to make sure that the manufacturer
22 of the resin did not know that it was going to be used
23 to be implanted in the human Board.

24 Q. (BY MR. BORANIAN) And that's an inference that
25 you're drawing about Bard's conduct and whether Bard

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1 bent over backwards based on your review of the Bard
2 company documents, right?

3 A. Yes, based on depositions of Bard's employees
4 and based on the written e-mails that are part of the
5 evidence in this case. I mean, that is not speculative
6 on my part.

7 I am reading that off of the papers that
8 were given to Bard -- given by Bard as a result of being
9 sued in this case. That -- this is not hearsay.

10 Q. So that's the -- but the opinion that you're
11 drawing is based only on your review of those documents
12 produced in discovery, right?

13 MR. POTTS: Objection. Objection; form.

14 Go ahead.

15 A. I don't have any other basis for making that
16 opinion.

17 But I will tell you that I think it's
18 incredible that the company that makes these devices
19 would sell this to physicians and not tell the
20 physicians, "Oh, by the way, Doc, it says you're not
21 supposed to put this inside the body, but we're going to
22 sell it to you anyway."

23 Q. When you make medical and scientific decisions,
24 Doctor, you base those decisions on information that has
25 clinical and scientific support, correct?

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1 **A. Yes.**

2 Q. Would you make a medical or scientific decision
3 based on information that has no clinical or scientific
4 support?

5 **A. No.**

6 Q. If there is no scientific support for the
7 medical application caution in the MSDS, you wouldn't
8 rely on that information, would you?

9 MR. POTTS: Objection; improper
10 hypothetical, calls for speculation.

11 **A. I am not sure that question is logically**
12 **consistent, but I cannot imagine somebody who is selling**
13 **a product for profit is going to put it out there and**
14 **say, "Don't use this product because we think it's not**
15 **safe."**

16 **Why do you make it? Why do you make it**
17 **and try to exclude it from being used as a medical**
18 **device, and why does Bard bend over backward to make**
19 **sure that the manufacturer is not to be made aware of**
20 **the fact that this is going to be put into the body?**

21 Q. (BY MR. BORANIAN) But you don't know why that
22 statement was put in that MSDS, do you?

23 **A. I am assuming that the manufacturer knew**
24 **something about the safety of the product. I don't know**
25 **why.**

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1 Q. But you're assuming that, right?

2 A. I am making that assumption, yes.

3 Q. Have you ever spoken with anyone at Phillips
4 about that?

5 A. Of course not.

6 Q. Have you ever spoken with anyone at Bard about
7 that?

8 A. No.

9 Q. Let me show you the deposition testimony,
10 Doctor, of a Phillips Sumika employee who was designated
11 as a corporate witness on this topic.

12 (Reeves Exhibit No. 15 was marked.)

13 Q. (BY MR. BORANIAN) This is Exhibit 15, Doctor.

14 Doctor, this is the deposition of Frank
15 Zakrzewksi, Z-a-k-r-z-e-w-s-k-i. It was taken in
16 relation to these pelvic mesh cases. And I will
17 represent to you that Mr. Zakrzewski was the witness
18 designated by Phillips Sumika to testify on behalf of
19 the MSDS medical caution.

20 Have you seen this testimony before?

21 A. No.

22 Q. Take a look at page 45. And there are four
23 pages on each page.

24 A. Understood.

25 Q. And starting on the last line of page 45,

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1 page -- line 24, page 45, it says, "Was the Medical
2 Application Statement that we've highlighted in
3 Deposition Exhibit 3 added to the polypropylene MSDS
4 based on any scientific testing that was conducted?"

5 Answer: "Not that I am aware of, no."

6 It goes on to say --

7 **A. Excuse me. May I just stop you for a second?**

8 You have lost me. I thought you said
9 you're on page 45.

10 What page are you reading from?

11 Q. Page 45 is -- is here, Doctor.

12 **A. Okay. All right.**

13 Q. And the very last line, line 24. And it --

14 **A. It goes up to the next top of the page. Okay.**

15 Q. Most scripts goes down.

16 **A. This goes up.**

17 Q. I apologize for that.

18 **A. Okay. Thank you.**

19 Q. And it says, "Was the Medical Application
20 Statement that we've highlighted in Deposition Exhibit 3
21 added to the polypropylene MSDS based on any scientific
22 testing that was conducted?"

23 Answer: "Not that I am aware of, no."

24 And it goes on to say, "And was the
25 Medical Application Statement for the polypropylene in

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1 the MSDS marked as Deposition Exhibit 3 added based on
2 any specific scientific data on polypropylene?"

3 Answer: "No, not that I am aware of."

4 If you go to page 47, Doctor, it says in
5 the middle on line 8, "Was the Medical Application
6 Statement that we're looking at in Deposition Exhibit 3
7 added to the polypropylene MSDS based on any review of
8 the scientific or medical literature on polypropylene?"

9 Answer: "Yeah. I am not aware of any
10 testing or information on polypropylene related to this
11 statement."

12 And it says, going on, "And was the
13 Medical Application Statement for the polypropylene
14 Material Safety Data Sheet added to the MSDS based on
15 any scientific concerns with vaginal mesh specifically?"

16 Answer: "No."

17 Did I read that correctly, Doctor?

18 **A. You did read that correctly.**

19 Q. So my question is, now that you know that the
20 Medical Application Caution was not based on any
21 scientific data or any testing or any medical literature
22 or any concern about polypropylene mesh, including mesh
23 used for -- for pelvic mesh products, does that affect
24 your opinion on whether or not this caution is relevant?

25 MR. POTTS: Just a minute. I have an

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1 objection to make.

2 First of all, the witness has not had an
3 opportunity to read the deposition. Second, it's a
4 mischaracterization of this witness' testimony.

5 On page 183 the witness is asked,
6 "There's no scientific basis for the statement in the
7 MSDS?"

8 Answer: "That would be speculation. I
9 don't know."

10 So this witness needs to be given an
11 opportunity to --

12 MR. BORANIAN: And it goes on to say,
13 "You're not aware of any?"

14 Answer: "I am not aware of any."

15 MR. POTTS: That's the basis for my
16 objection.

17 Cherry picking statements is improper.
18 He needs an opportunity to read the deposition in its
19 entirety to make a fair assessment of the evidence.

20 Q. (BY MR. BORANIAN) The Medical Safety Data
21 sheet, Doctor, is a pretty important part of the record,
22 wouldn't you say?

23 A. It is.

24 Q. It's the first thing you talk about in your
25 report, right?

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1 **A. It is, yes.**

2 Q. Were you provided this deposition transcript to
3 review?

4 **A. No.**

5 Q. So even though you were giving opinions, and
6 the attorneys who hired you knew you were giving
7 opinions about the MSDS, they did not provide to you
8 testimony from a witness from the company who was
9 designated to talk about that Data Sheet, correct?

10 MR. POTTS: Objection; asked and
11 answered.

12 **A. No. I have not seen this before today.**

13 Q. (BY MR. BORANIAN) And did you ask for any
14 additional information about the
15 Material Safety Data Sheet before you formed your
16 opinions?

17 **A. I did not.**

18 Q. So you didn't take this testimony into account
19 in forming your opinions, right?

20 **A. I hadn't seen it.**

21 Now, the other thing I am going to
22 represent to you is this is a company spokesperson, and
23 I have no reason to believe or disbelieve his veracity
24 on the subject. I don't know whether he's telling the
25 truth or not, and I don't know whether or not counsel

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1 for the opposition had a chance to drill him and see
2 that what he was saying was the truth.

3 What I -- what I will also say is, why
4 would a company allow an MSDS sheet like this to be
5 published if it was going to be detrimental to their
6 business? That flies in the face of any sound economic
7 basis for selling the product.

8 Q. Do you know what portion of this --

9 A. I have no clue.

10 Q. So you're really speculating aspect to its
11 impact on its business?

12 A. No, I am not speculating.

13 I am saying it's stupid to put a product
14 out for use in the body that you're saying is unsafe
15 if you're going to -- and why do you -- why did Bard go
16 to such an effort to make sure that the manufacturer was
17 not going to know that this was going to be used in the
18 body?

19 Q. And that's an inference that you've made based
20 on your review of company documents, right?

21 A. And based on the depositions and based on the
22 e-mails.

23 Q. But you have not talked to any of those people
24 in person, correct?

25 A. No, I haven't.

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1 Q. And you -- all of the reservations or concerns
2 that you have expressed about this transcript, you were
3 not even given a chance to review the transcript before
4 today, were you?

5 A. You have already asked me that once before, and
6 the answer is still the same.

7 The answer is no.

8 Q. Now, it goes on to say on page 168 on --

9 A. You said 68, or 168?

10 Q. 168, Doctor. I am sorry.

11 A. Okay.

12 Q. On line 20, it says, "Did Phillip Sumika expect
13 the end processors to make the determination as to the
14 suitability of using Marlex resin for whichever
15 application they choose," and the answer is, "Yes."

16 And it goes on to page 169: "And did
17 Phillips Sumika expect the end processor to conduct
18 whatever testing was necessary to ensure that it was
19 suitable for the application they choose?"

20 And the answer is, "Yes."

21 Now, you have -- we have established that
22 you haven't had a chance to take that into account
23 before today, Doctor.

24 But let me ask you this: Have you
25 reviewed the testing that Bard has done on its Marlex

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1 polypropylene medical devices over the years?

2 **A. No.**

3 Q. And are you aware that Bard has been using
4 Marlex polypropylene for human implant since the 1960s?

5 **A. Yes.**

6 **In fact, I will go you one further:**
7 **Marlex was actually developed initially by a Houston**
8 **surgeon named Usher. The product originated in Houston,**
9 **the prototypes did.**

10 Q. That was back in 1958, right?

11 **A. Usher goes back to '58, yes.**

12 Q. And Dr. Usher, in fact, was published in 1962
13 and 1963 about the use of Marlex mesh in -- in human
14 implantation, right?

15 **A. That's correct.**

16 Q. So in forming your opinions, did you ask
17 counsel to provide you information about the testing
18 that Bard had done to determine the suitability of
19 Marlex polypropylene resin for medical devices?

20 **A. I did not.**

21 Q. When did you first see the MSDS in this case?

22 **A. When I got the documents from the**
23 **Potts Law Firm, and I am going to go back probably to**
24 **September for that.**

25 Q. Have we marked -- I don't think we have marked

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1 that.

2 Is this it, Doctor?

3 (Reeves Exhibit No. 16 was marked.)

4 Q. (BY MR. BORANIAN) This is Exhibit 16, Doctor.
5 It is a Material Safety Data Sheet, and the date is --
6 at the very bottom is December 4th, 2008.

7 Is this the MSDS that you reviewed?

8 **A. Yes.**

9 Q. And it says here in the middle of the page,
10 "Medical Application Caution."

11 Is that the Medical Application Caution
12 that you quoted in your report?

13 **A. Yes.**

14 Q. Is there any citation to any scientific or
15 medical literature in connection with this
16 Medical Application Caution?

17 **A. Not that I am aware of.**

18 Q. Now, it says in the caution -- it says, "Do not
19 use this Phillips Sumika Polypropylene Company material
20 in medical applications involving brief or temporary
21 implantation in the human body or contact with internal
22 body fluids or tissues unless the material has been
23 provided directly from Phillips Sumika Polypropylene
24 Company under an agreement which expressly acknowledges
25 the contemplated use."

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1 Is that what it says?

2 A. That's what it says.

3 Q. So this sheet actually contemplates that it
4 will be used in implantable form in humans, at least in
5 some forms, right?

6 MR. POTTS: Objection; form. The
7 document speaks for itself.

8 A. Yeah.

9 I am not sure that I can second guess
10 what they're saying here. I can read it just as well as
11 you can, Counselor, but I don't know what they plan to
12 do with it.

13 I will take you back to the first
14 paragraph which says, "Do not use this material in
15 medical applications involving permanent implantation in
16 the human body or permanent contact with internal body
17 fluids or tissue."

18 I don't think that could be clearer.

19 Q. (BY MR. BORANIAN) Right. That is the
20 statement that we're searching for some scientific or
21 medical support for that so far I haven't seen.

22 But the paragraph beneath that suggests
23 that the -- the product can be used in implanted form in
24 human tissue, right?

25 MR. POTTS: Object to the form of the

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1 question.

2 In temporary implantation.

3 A. We can both read what the paragraph says.

4 I don't know how long they intend its use
5 or not. I will take you back to the first paragraph
6 where they said, "Don't put it in."

7 Q. (BY MR. BORANIAN) They say it can be used in
8 implantation if certain conditions are met, right?

9 Is that a fair characterization?

10 A. Unless the material has been provided directly
11 from Phillips Sumika under an agreement which expressly
12 acknowledges the proper use. Those are the conditions
13 that they place on its use.

14 Q. And beneath that, it says that the company
15 makes no representation, promise, express warranty, or
16 implied warranty concerning the suitability of this
17 material for use in implantation in the human body or in
18 contact with internal body fluids or tissues.

19 That's what it says, correct?

20 A. That's what it says.

21 And it seems to me that you can infer
22 from the paragraph that the responsibility for this
23 product would rest solely and completely with the
24 company that manufactures the product.

25 Q. But Phillips Sumika is making no representation

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1 regarding the suitability of the material for use,
2 correct?

3 **A. That's what they say.**

4 Q. Now, at the bottom of this page, Section 2 is a
5 section called, "Hazard Identification," right?

6 **A. Right.**

7 Q. Does this section lists implantation in the
8 human body as a hazard?

9 **A. They're talking about contact with eyes or skin
10 or ingestion or inhalation.**

11 Q. But there's no mention of a hazard in
12 connection with implantation in the human body, is
13 there?

14 **A. I do not see it.**

15 Q. And if you go to the last page of the MSDS,
16 here there is actually a black box, correct?

17 **A. Are you on page 8 of 9?**

18 Q. I am on page 9 of 9.

19 **A. 9 of 9, okay. I am with you.**

20 Q. And the last thing this says is that this
21 information is furnished upon condition that the person
22 receiving it shall make his own determination as to the
23 suitability of the material for its particular purpose.

24 That's the last word, right?

25 **A. That's what it says.**

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1 Q. So Phillips Sumika is saying in this statement
2 that it's up to the user of the resin to determine its
3 suitability for use, correct?

4 MR. POTTS: Object to the form of the
5 question, conclusion as to what Phillips Sumika intended
6 to say, and the document speaks for itself.

7 A. I think it says what it says.

8 Q. (BY MR. BORANIAN) It's up to the end user to
9 determine the suitability, right?

10 MR. POTTS: Same objection.

11 A. I can read this sentence back to you, and we
12 can determine what it means like we wish to determine
13 what it means.

14 They are laying a particular load on the
15 end-use manufacturer; I don't think there's any question
16 about that.

17 Q. (BY MR. BORANIAN) Do you know if the
18 Phillips Sumika Material Safety Data Sheet has always
19 included the Medical Application Caution?

20 A. I do not.

21 (Reeves Exhibit No. 17 was marked.)

22 Q. (BY MR. BORANIAN) This is Exhibit 14.

23 A. May I make an observation, that we've gone to
24 16, and now we're going back to 14?

25 Did you mean to do that?

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1 (Brief discussion off the record.)

2 A. I just want to make sure we're on the same page
3 literally.

4 Q. (BY MR. BORANIAN) This is an MSDS for Marlex
5 polypropylene dated February 15, 1993, correct?

6 A. That should exceed the statute of limitations,
7 shouldn't it?

8 Q. That's correct.

9 Right, Doctor?

10 A. That's what it says.

11 Q. And this does not contain any caution regarding
12 implants in humans, does it?

13 MR. POTTS: Well, do you want to give him
14 a chance to read it?

15 A. Yeah. I -- I have seen this for ten seconds.

16 Do you mind if I flip through it for a
17 second?

18 Q. (BY MR. BORANIAN) Take your time.

19 A. All right.

20 Q. Just Have my question in mind while you're
21 doing that.

22 A. Okay. After a brief 20-second perusal of this
23 document, I do not see any information referring to
24 whether it should or shouldn't be placed in the human
25 body.

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1 Q. If you look at page 3 of Exhibit 17, under the
2 health hazard data, it says in the middle of the page,
3 "Ingestion: Essentially nontoxic and insert."

4 Is that what it says, Doctor?

5 A. You said page 3?

6 Q. Yeah, page 3 in the middle of the page under,
7 "Health Hazard Data," the word, "Ingestion."

8 A. Oh, ingestion? Yes, I see it. Essentially
9 nontoxic and inert.

10 Q. I understand that ingestion is not the same as
11 implantation, Doctor.

12 But my question is, do you agree that
13 this -- this version of the MSDS dated 1993 does not
14 suggest that Marlex polypropylene resin is inappropriate
15 for use in humans?

16 A. You're asking me about data that is 21 years
17 old, and this 21-year-old document, if you want to
18 introduce this into evidence, something that is
19 antiquated, doesn't indicate that there's a problem.

20 I think it's extraordinary that anybody
21 would rely on a document this old. But if you want to
22 introduce this into evidence, be my guest.

23 Q. Well, let's take a look at this one, Doctor.

24 (Reeves Exhibit No. 18 was marked.)

25 Q. (BY MR. BORANIAN) This is Exhibit 18, Doctor.

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1 And this is a Marlex polypropylene Material Safety Data
2 Sheet from 1997.

3 Now, Doctor, by 1997, polypropylene had
4 been used in implanted medical devices for about
5 40 years, right?

6 **A. Yes.**

7 Q. Because of Dr. Usher's pioneering work here in
8 Houston, correct?

9 **A. Correct.**

10 Q. Doctor, my question is, does this document have
11 a medical caution like the one we've seen earlier? And
12 you can take your time and look at it, but that's my
13 question, Doctor.

14 **A. It looks like if you're a fish or a bird, you**
15 **have a problem, but I don't see anything related to**
16 **human implantation in this document.**

17 Q. So this MSDS dated 1997 does not suggest that
18 the use of Marlex polypropylene resin is not appropriate
19 for humans, right, for implantation of humans?

20 **A. It doesn't discuss it.**

21 Q. Have you reviewed the
22 Material Safety Data Sheets for materials used by other
23 vaginal mesh manufacturers?

24 **A. I have not.**

25 Q. Do you know if other manufacturers use the same

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1 Marlex polypropylene raw pellets as Bard?

2 **A. I do not.**

3 Q. Do you know whether the FDA has asked anybody
4 about the Material Safety Data Sheet?

5 **A. I do not.**

6 (Reeves Exhibit No. 19 was marked.)

7 Q. (BY MR. BORANIAN) This is Exhibit 19, Doctor.

8 Before we get to this, Doctor, let me ask
9 you, were the 1993 and 1997 Material Safety Data Sheets
10 provided to you by counsel for review?

11 **A. They were not.**

12 Q. So prior to today, you were unaware that the
13 caution was added sometime between 1997 and 2008,
14 correct?

15 **A. That's correct.**

16 Q. And so because of that, you were unable to take
17 that into account in forming your opinions, right?

18 **A. By definition, that's correct.**

19 Q. So this Doctor, is Exhibit 19. It's
20 correspondence between the Department of Health & Human
21 Services/FDA and Boston Scientific.

22 If you turn to page 5 according to the
23 numbers down in the lower right-hand corner --

24 **A. I am with you.**

25 Q. Well, I am sorry. Go back to page 1. I

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1 apologize, Doctor.

2 Let's establish that this is a letter to
3 Boston Scientific to someone named Berry, Michelle
4 Berry. And at the beginning, it says, "We have reviewed
5 your Section 510(k) premarked as notification of intent
6 to market the device referenced above. We cannot
7 determine if the device is suitably equivalent based
8 solely on the information you provided."

9 And then they go on to ask for additional
10 information, correct?

11 **A. It looks like it.**

12 Q. And the product that is referenced is the
13 Pinnacle Pelvic Floor Repair Kit 2, right?

14 **A. I don't see that on page 1.**

15 Q. That's under the subject, "Re," the re line.

16 **A. I see you. I am with you.**

17 **Yes.**

18 Q. Okay. So one of the things they asked about is
19 on page 5, Doctor. It's in the paragraph numbered 8.
20 And it says, "The Material Safety Data Sheet, MSDS,
21 provided for the Marlex material states that the product
22 use is for coatings. In this MSDS, there is a
23 Medical Application Caution that states" -- and then it
24 quotes the caution, correct, Doctor?

25 **A. Correct.**

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1 Q. And the FDA says, "Please provide a rationale
2 why your mesh material is safe for use as a permanent
3 implant device contrary to what is stated in the MSDS in
4 the Marlex material."

5 That's what it says, right?

6 **A. Right.**

7 Q. So the FDA was aware of the MSDS and asked for
8 more information, right?

9 MR. POTTS: I will object.

10 But second of all, it's a 22-page
11 document from another M.D.L. this witness has not had a
12 chance to review. And to ask questions about it based
13 upon what you've been cherry picking a few lines is
14 improper. It should not be done.

15 Further, I am going to object that the
16 question at issue asks for the state of the mind of the
17 FDA and a legal conclusion.

18 Go ahead.

19 Q. (BY MR. BORANIAN) You can answer the question.

20 Do you want me to ask it again?

21 **A. Please.**

22 Q. I will ask it a different way.

23 In this letter dated June 17th, 2008, the
24 FDA refers to the Medical Application Caution that is
25 the subject of your report, correct?

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1 **A. Correct.**

2 Q. If you turn to page 9, Doctor --

3 **A. I was on page 5.**

4 **Are you leaving 5?**

5 Q. I am leaving 5.

6 Actually, go to page 8.

7 **A. Okay. I am on page 8.**

8 Q. And this is Boston Scientific's response dated
9 July 18, 2008, correct?

10 **A. It looks like it.**

11 Q. And then go to page 9, Doctor.

12 And the author of this letter has
13 restated FDA Question No. 8, which is the one we just
14 were talking about, correct?

15 **A. Correct.**

16 Q. And they respond, "Marlex HGH-030-01
17 Polypropylene Homopolymer resin has been used by Boston
18 Scientific for permanent implant since the late 1990s.
19 From the late 1990s until early 2000, the resin was
20 purchased from Phillips Sumika and spun into fiber at
21 Shakespeare Monofilament acquired by Jarden in
22 April 2007."

23 That's what it says, right, Doctor?

24 **A. You read that correctly, Counselor.**

25 Q. Is this the same polypropylene mesh that Bard

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1 was using -- I am sorry -- polypropylene resin that Bard
2 was using?

3 **A. You're asking me about Boston Scientific and I**
4 **am assuming that's the case, but I don't have any direct**
5 **knowledge of that.**

6 MR. POTTS: Objection; calls for
7 speculation.

8 Q. (BY MR. BORANIAN) At the bottom of page 9
9 above the heading, "Safety Testing," it says that
10 Boston Scientific has performed extensive testing to
11 support that the material is safe for use as a long-term
12 permanent implant device.

13 That's what it says, right?

14 **A. That's what it says.**

15 Q. And it goes on to the next page and a little
16 more than a page describing the testing, correct?

17 **A. It does.**

18 Q. Go to page 12, Doctor.

19 This is the FDA's response dated
20 August 22nd, 2008, and the FDA approved the 510(k)
21 Premarket Notification, correct?

22 **A. I have had five seconds to look at this page.**

23 Q. Take your time, Doctor.

24 This was not provided to you earlier?

25 **A. No. I haven't seen this before.**

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1 MR. POTTS: Why would we provide a Boston
2 Scientific document?

3 Q. (BY MR. BORANIAN) This discusses the
4 Medical Application Caution that's at the core of your
5 opinion, right?

6 A. Yes.

7 Q. But it wasn't provided to you in forming your
8 opinions, right?

9 A. You're making the assumption from me that what
10 Boston Scientific is using and what they've made is
11 identical to what Bard did, and I have no way of knowing
12 that.

13 Q. Well, I am just asking you a few questions
14 about it.

15 A. Well, you're asking me to make assumptions, and
16 I haven't had a chance to read it.

17 Q. Well, we've gone through the exchange.

18 And my question is, after the exchange
19 that we've gone through, the FDA approved the 510(k)
20 notification? That's the questioning pending.

21 MR. POTTS: I will object and instruct
22 the witness not to answer until he can read it. If you
23 want to spend your time with 30 minutes to read the
24 document, we'll do that.

25 He's not going to answer the question --

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1 if you want to stop and let him read the document, we'll
2 stop, and you can reconvene.

3 MR. BORANIAN: Well, I have not cherry
4 picked.

5 I have shown him everything in these
6 documents that relates to the Question No. 8 about the
7 Application Caution. I also have afforded the Doctor an
8 opportunity to review the documents. I have not denied
9 him when he's requested it.

10 And I asked a simple question, the FDA
11 approved the application? That's the question pending.

12 MR. POTTS: He's not going to answer a
13 question unless you stop and let him read the document.

14 Q. (BY MR. BORANIAN) Doctor, do you need 30
15 minutes to review this document?

16 MR. POTTS: Well, whatever it takes.

17 If we're going to get into this, he's
18 going to read the document. He's not going to rely on
19 your interpretation of the document to answer the
20 question.

21 Make a decision. If you want him to
22 answer the question, take a break.

23 A. When I prepared for being involved with this as
24 an expert witness, you can see from the notes I made on
25 these articles that I went through them line by line

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1 with a red pen, and I read these things carefully before
2 I came to any conclusions.

3 You have been asking me about this
4 particular document which has in toto, I am going to
5 guess, probably 15 pages. I have had this in my hand
6 for less than 5 minutes, and I cannot begin to give you
7 a valid answer when I have had this for 5 minutes.
8 That's not the way I read medical literature or reports
9 and garbage and verbiage from the FDA.

10 MR. POTTS: Enough.

11 So if you want him to answer the
12 question, we'll take a break. If not, we'll move on.
13 Let us know.

14 Q. (BY MR. BORANIAN) Do you need a break to
15 answer the question whether Boston Scientific reviewed
16 and approved the application?

17 A. If you want an opinion about this document, I
18 need to read it.

19 Q. Which tells us you did not have a chance to
20 read it before, right?

21 A. I haven't seen it before.

22 Q. Okay. The question pending is, after the
23 exchange, did the FDA approve the 510(k)?

24 MR. POTTS: I will instruct him not to
25 answer until he can read the document.

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1 MR. BORANIAN: You can take a break.

2 MR. POTTS: Let's go off the record.

3 THE VIDEOGRAPHER: We are off the record.

4 The time is 1:53 p.m.

5 (Recess from 1:53 p.m. to 2:0 p.m.)

6 THE VIDEOGRAPHER: We are back on the
7 record. The time is 2:05 p.m.

8 MR. BORANIAN: Will you re-read the
9 question, please?

10 (Requested portion was read.)

11 MR. POTTS: Subject to the following
12 objections: One, this is improper using a document from
13 another M.D.L. This Court has specifically said that
14 should not be done.

15 In addition, the Court has ruled FDA
16 evidence is not admissible in the M.D.L.

17 Third, it calls for speculation.

18 And fourth, the document speaks for
19 itself.

20 Subject to those objections, you may
21 answer.

22 **A. The FDA did not approve it; the FDA cleared it.**
23 **And there's a substantial difference.**

24 **So the answer to your question is no.**

25 Q. (BY MR. BORANIAN) Well, I did say 510(k)

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1 premarket notification.

2 **A. Okay.**

3 Q. Did the FDA give Boston Scientific permission
4 to legally market this device under the Section 510(k)
5 premarket notification process?

6 **A. Yes, they did.**

7 Q. And you have not had a chance to see any of the
8 testing that --

9 **A. No.**

10 Q. -- that Boston Scientific describes, have you?

11 **A. No.**

12 Q. And that's similar to Bard: You haven't had a
13 chance to see what testing Bard has done on
14 polypropylene, have you?

15 **A. I have not.**

16 Q. Doctor, under this -- going on in your report
17 under the same section you've been discussing, you give
18 an opinion regarding -- on page 9, something about
19 information not being disclosed being especially
20 concerning in light of literature showing reports of
21 cancer associated with polypropylene.

22 Doctor, is the risk of cancer part of the
23 basis for your opinions today?

24 **A. Only -- I think I am not ever suggesting that**
25 **polypropylene causes cancer.**

1 There are three reports in the literature
2 in this stack that describe an association -- not cause
3 and effect, but an association of women who had mesh
4 devices implanted who go on to develop malignancy.

5 I am not saying that there's demonstrable
6 proof of cause and effect.

7 Q. You cannot say, then, to a reasonable degree of
8 medical certainty that polypropylene creates the risk of
9 cancer, can you?

10 A. I cannot say that.

11 Q. So looking at your report, Doctor, which of
12 these citations in footnotes 1, 2, 3, 4, 5, and 6 are
13 the case reports that you're referring to?

14 A. The last three: Ahuja, Moller, and Ben-Izhak
15 are the ones I am talking about.

16 Q. So in footnote 1, Kassem and Mehrotra and Kwon,
17 those don't involve reports of cancer, do they?

18 A. I don't think so.

19 I would have to look at those
20 specifically to be sure about that.

21 See, the first one is pseudotumor, and
22 that's not a malignancy, and Kwon is an inflammatory
23 myofibroblastic tumor of low malignant potential. Those
24 are not cancers.

25 Q. I have the documents here, Doctor, but I hate

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1 to spend the time going through it if I don't have to --

2 A. I don't think it's necessary.

3 Q. -- if we agree.

4 Do we agree that the first -- that the
5 reports in footnotes 1 and 2, Kassem, that row the and
6 Kwon do not report cancer?

7 A. I agree with that.

8 Q. Okay. Thanks.

9 I will show you the Ahuja article,
10 Doctor.

11 (Reeves Exhibit No. 20 was marked.)

12 Q. (BY MR. BORANIAN) This is Exhibit 20.

13 A. I got it in here. I have already seen it, but
14 I will look at it again.

15 Q. You can look at whatever copy you like, Doctor.

16 A. I am going to look at mine because it's marked.

17 Q. Okay. That's fine.

18 So Ahuja is a report of two cases, right?

19 A. Yes.

20 Q. And I should say for the record, Exhibit 20 is
21 Ahuja 2011, "Bowel Cancer and Previous Mesh Surgery,"
22 right?

23 A. Right.

24 Q. So case 1 is a case following abdominal sacral
25 colpopexy using Mersilene mesh, right?

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1 **A. Correct.**

2 Q. Mersilene is not polypropylene, correct?

3 **A. Mersilene is Mersilene.**

4 Q. Okay. And case 2 is following an anterior --
5 say it again for me, Doctor.

6 **A. "Colporrhaphy."**

7 Q. "Colporrhaphy."

8 -- and a sacral colpopexy, among other
9 procedures using polypropylene mesh, right?

10 **A. Right.**

11 Q. So this is one Case Report of a cancerous tumor
12 involving polypropylene, right?

13 **A. Right.**

14 Q. And Dr. Ahuja and his colleagues -- maybe it's
15 him -- colleagues, their opinion is that it's unlikely
16 that the bowel cancer was caused by the mesh, right?

17 **A. The last sentence in their abstract states,
18 quote, "It is unlikely that the mesh is a causative
19 agent in the above cases," closed quote.**

20 Q. So Ahuja is one case report.

21 And then let's take a look at Moller. I
22 will mark it as Exhibit 21, Doctor, but you can look at
23 whatever copy you want.

24 **A. I have got it in my binder.**

25 (Reeves Exhibit No. 21 was marked.)

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1 Q. (BY MR. BORANIAN) Now, Moller involves
2 implantation of the Bard Duraderm product, right?

3 A. Correct.

4 Q. And that is not polypropylene, is it?

5 A. That is correct.

6 Q. So this is a Case Report of what, Doctor?

7 A. A vaginal leiomyosarcoma.

8 Q. And that is a form of cancer, correct?

9 A. It is.

10 And it's an extraordinary rare
11 malignancy, for the record.

12 Q. This is not polypropylene mesh, right?

13 A. It is not polypropylene mesh.

14 Q. Okay. And then you also cited Dr. Binnebosel?

15 A. Yes.

16 (Reeves Exhibit No. 22 was marked.)

17 Q. (BY MR. BORANIAN) We'll call this Exhibit 22,
18 Doctor.

19 A. Okay.

20 Q. And Exhibit 22 is, "Epithelioid Angiosarcoma
21 Associated with a Dacron Vascular Graft."

22 And for the record, Exhibit 21 was Karen
23 Moller primary -- say that again for me, Doctor.

24 A. Was that the angiosarcoma?

25 Q. Lei --

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1 **A. Leiomyosarcoma.**

2 Q. L-e-i-o --

3 **A. Leiomyosarcoma.**

4 Q. Of the vagina?

5 **A. Right.**

6 Q. So back on Exhibit 22, Dr. Ben-Izhak, this
7 involved a Dacron polyester graft, right?

8 **A. Right.**

9 Q. That's not polypropylene?

10 **A. It is not.**

11 **It is Dacron.**

12 Q. Okay. So we have one Case Report of cancer
13 with polypropylene and then two others with other
14 products, right?

15 **A. That is correct.**

16 Q. And then you also cited an IARC monograph.

17 Are you familiar with that, Doctor?

18 **A. Can you be a little more specific for me, IARC?**

19 Q. Sure. I can show it to you.

20 (Reeves Exhibit No. 23 was marked.)

21 Q. (BY MR. BORANIAN) This is Exhibit 23, Doctor.

22 Does that ring a bell?

23 And I will tell you, those are excerpts.
24 The actual monograph is much, much larger.

25 **A. Okay.**

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1 Q. You may recognize it as a larger book.

2 A. Okay. Go for it.

3 Q. So Exhibit 23 is excerpts from the IARC
4 Monographs on the Evaluation of Carcinogenic Risks to
5 Humans, right?

6 A. Right.

7 Q. And the part that you cited from your report is
8 the summary which starts at page 303 of these excerpts.
9 The pages are in sequence, but they're not all there.

10 A. I am on 303.

11 Q. So -- and this is the part that you cite in
12 your report, Doctor. I think it's in footnote 6.

13 A. Okay.

14 Q. This is reporting on exposure data, including
15 to polypropylene, correct?

16 A. They're talking, yes, polypropylene in the form
17 of -- they're saying specifically sutures, prosthetic
18 joint components. I think those were the things they're
19 talking about.

20 Q. Well, the prosthetic joint components are
21 polypropylene, right, on 303?

22 A. I am looking at 303, polyethylene sutures for
23 polypropylene and polyethylene, that's correct. That's
24 right.

25 Q. Okay. Doctor, have you seen this document

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1 before?

2 A. No.

3 Q. So did you prepare this document?

4 A. I may not have prepared this sentence.

5 Q. Who prepared this portion of your report?

6 A. I am not sure.

7 Q. Someone at the Potts Law Firm?

8 A. Yes.

9 Q. So do you have an opinion either way on whether
10 this document we're looking at, Exhibit 23, supports or
11 does not support any opinion?

12 A. I think it's talking about -- I said to begin
13 with I am not postulating a cause and effect here
14 between polypropylene and malignancy.

15 Q. Okay. Well, there's no human data in this
16 document about polypropylene and cancer, is there?

17 A. I have not seen this document. I don't know
18 the answer to your question.

19 I am -- based on what I have seen, I will
20 repeat for the third time, I am not postulating a
21 cause-and-effect relationship between polypropylene and
22 human cancer.

23 Q. Good. Let's move on.

24 Doctor, do you believe that Bard should
25 warn about the risk of cancer in connection with its

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1 polypropylene products?

2 A. That's a good question. I -- I think it's an
3 open-ended question.

4 I think we don't have lifetime data for a
5 lot of people. I think to date, there has not been any
6 documented cause-and-effect relationship proven between
7 polypropylene and cancer.

8 Q. So upon what data would you think that -- well,
9 why is it an open question?

10 A. Well, because --

11 Q. If there's no data, why is there an open
12 question?

13 A. It's because we've only got data that goes back
14 -- specifically with regards to the devices in the
15 pelvis, which is my area of expertise, okay, this has
16 only been used now since the 1990s. So we've got 20
17 years of data.

18 We don't have anybody who is walking
19 around who has had vaginal mesh products inside them for
20 30 years now. So I am not trying to be cutesy with you.

21 I am just telling you that based on the
22 data we have, there's no proof that there's a
23 cause-and-effect relationship.

24 Q. To date?

25 A. To date.

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1 **Could something show up at some point in**
2 **the future? I think that's a possibility. Do I know**
3 **what' going to happen? No, I don't.**

4 Q. So is it fair to say that there's no basis upon
5 which to warn about a risk of cancer and polypropylene
6 today, but you don't know what's going to happen in the
7 future?

8 Is that fair to say?

9 **A. That's fair to say.**

10 Q. And you're familiar with -- with the AUGS'
11 position on this, correct?

12 **A. Specifically?**

13 Q. AUGS' position is that there's no evidence that
14 any women have developed cancer in connection as a
15 result of a midurethral sling.

16 You would agree with that?

17 **A. I would agree with that.**

18 Q. And none of the individual plaintiffs on which
19 you are providing case-specific opinions have cancer, do
20 they, to your knowledge?

21 **A. To my knowledge, no.**

22 Q. And you will not be opining that polypropylene
23 has caused them cancer, correct?

24 **A. No, I will not.**

25 Q. Okay. Let's go back to your report, Doctor.

1 On to page 12, there's a heading
2 entitled, "Section B."

3 **A. I see it.**

4 Q. Doctor, is that an opinion that you intend to
5 give in this litigation?

6 **A. It is.**

7 Q. And the opinion is that Bard's Align mesh is
8 not suitable for its intended application as a permanent
9 prosthetic implant for SUI in the human body due to its
10 frequency to curl, closed quote, also known as, quote,
11 cording, closed quote, and, slash, roping, closed quote,
12 comma, as well as fraying during and after placement in
13 the body making, thus making its design defective and
14 make it unreasonably dangerous.

15 Is a that what you wrote, Doctor?

16 **A. That's what I wrote.**

17 Q. Is that your opinion?

18 **A. Yes.**

19 Q. Now, you described to us some of your
20 experience designing medical devices, but have you ever
21 designed a mesh device?

22 **A. No.**

23 Q. Do you have any formal education regarding
24 biomedical engineering or biomechanics?

25 **A. No.**

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1 Q. Do you have any other kind of training
2 regarding biomedical engineering or biomechanics?

3 A. No.

4 Q. Now, did you personally do any testing on the
5 Align product in forming your opinion that the product
6 was prone to curling, cording, roping, and/or fraying?

7 A. All you have to do is to use this stuff and
8 play with it, and you can make it happen by putting
9 tension on it. And after it's been in the body, when --
10 when we take it out, you can see what's happened to it.

11 And it has a tendency after its been in
12 the body not to be flat, but to be curled up. It will
13 also do this (indicating).

14 The longer it's in the body, the more
15 these edges get frayed, and it deteriorates, and it
16 doesn't stay in the body like it was put in by the
17 operating surgeon.

18 Q. So let me explore this a little further,
19 Doctor.

20 A. Please.

21 Q. So the basis of your opinion that the Align
22 device is prone to curling, cording, roping, and fraying
23 is, number one, your manipulation of the device you're
24 holding in your hand right now?

25 A. Right.

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1 Q. And your observations when explanting slain
2 meshes, correct?

3 A. Correct.

4 Q. Are there any other bases for your opinions?

5 A. No.

6 Q. So you have described your manipulation of the
7 device as, you know, playing around with it, right?

8 A. Right.

9 Q. So you manipulated it. You pulled on it.

10 What else have you done to it?

11 A. Nothing.

12 Q. So did you -- I mean, you gave me that response
13 in response to my question about testing.

14 A. Right.

15 Q. So let me ask you about testing.

16 Did you ever have -- did you put together
17 any protocol or plan before you held the device and
18 manipulated it?

19 A. No.

20 Q. Did you have any controls or any comparison
21 groups, you know, one group versus another versus
22 another, that kind of thing?

23 A. No.

24 Q. Did you measure the force that you applied as
25 you were manipulating the mesh?

1 **A. No.**

2 Q. And you never actually implanted an Align mesh,
3 right?

4 **A. I have not.**

5 Q. So you haven't personally handled the mesh
6 during an implantation procedure, right?

7 **A. I have not.**

8 Q. So you're not familiar with the feel of the
9 mesh as you've implanted it or pulling it through the
10 incision?

11 You have no personal experience with that
12 kind of thing, right?

13 **A. Well, I have first assisted lots of urologists**
14 **as they were doing it, so I have seen the process done,**
15 **but I have not physically done it myself.**

16 Q. You haven't physically pulled the mesh through
17 the incision, right?

18 **A. I have not.**

19 Q. So you're not familiar with the amount of force
20 that's required to do that procedure, are you?

21 **A. Not on the basis of my personal experience.**

22 Q. Now, when you were doing the manipulation and
23 the holding of the mesh, did you record any results of
24 your experience?

25 **A. No.**

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1 Q. Did you take any notes?

2 A. No.

3 Q. Now, in this particular portion of your report,
4 Section B, you don't site any medical literature; is
5 that right, Doctor?

6 A. That's right.

7 Q. Will you be relying on medical literature in
8 supporting -- well, strike that.

9 Did you rely on medical literature in
10 forming your opinion regarding cording, fraying, roping,
11 and curling?

12 A. No.

13 That is clinical experience. That is
14 based on what it looks like when I have taken it out.

15 Q. You have, however, reviewed documents produced
16 in discovery, right, company documents?

17 A. Yes.

18 Q. And you're basing your opinion in part on those
19 documents, correct?

20 A. Yes.

21 Q. So it's fair to say that this particular
22 opinion on the design of the Align mesh is based on Bard
23 documents and your personal observations, right?

24 A. That's correct.

25 Q. And nothing else, right?

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1 **A. Correct.**

2 Q. And you say that Bard was aware of the risk of
3 curling, cording, roping, and fraying?

4 Is that your opinion, Doctor?

5 **A. That's correct.**

6 Q. And you're forming that opinion based, again,
7 on your review of Bard documents, right?

8 **A. That is right.**

9 Q. Now, the Bard documents that you cite in your
10 report, they say that the Align was designed to prevent
11 cording, correct?

12 **A. Can you cite me chapter and verse what you're**
13 **asking about, please?**

14 Q. Well, I can just read from your report.

15 It says on the bottom of page 12, which
16 is where we currently are --

17 **A. Okay.**

18 Q. -- that a slide entitled, "Mesh Design," stated
19 that the mesh design of Align had, quote, improved
20 recovery to prevent cording, and that when used in
21 cadaver labs, the mesh had laid very flat on the
22 urethra.

23 That's what you wrote, right?

24 **A. Right.**

25 Q. And it goes on to say, "We designed the new

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1 mesh with optimal integrity for optimal functionality
2 under the urethra. In particular, the stability of the
3 mesh was improved to prevent cording."

4 So I am just relying on your
5 characterization of the documents.

6 **A. Okay. That's fair.**

7 Q. Do you know exactly what Bard did in the design
8 process to address this issue?

9 **A. No.**

10 Q. You also say that Bard received complaints, and
11 we're looking now at page 14 of your report right at the
12 top. You say, "Bard received 197 complaints related to
13 failures of various aspects of the Align product."

14 Is that what it says, Doctor?

15 **A. It does.**

16 Q. And did you review those complaints?

17 **A. No.**

18 That comes -- that comes from Frytag's
19 deposition. That number came from his deposition.

20 Q. You have something else cited here, too. We
21 can pull that document out and show it to you.

22 (Reeves Exhibit No. 24 was marked.)

23 Q. (BY MR. BORANIAN) This is Exhibit 24, Doctor.

24 Have you seen this document before?

25 **A. I do not recall having seen this document.**

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1 Q. But it is cited in your report, right?

2 A. Okay.

3 Q. So who prepared that citation in your report to
4 this document?

5 A. I do not know.

6 Q. So someone at the Potts Law Firm, right?

7 A. Yes.

8 Q. Okay. If you look at the page 4 of 13 in what
9 we've numbered Exhibit 24, this says down here on
10 No. 10 --

11 A. Right.

12 Q. Do you see that?

13 A. Yes.

14 Q. That -- that's the 197 complaints, right?

15 A. Right.

16 Q. And that lists a variety of different --
17 different complaint natures, including connector broke
18 during needle passage.

19 Let me just ask you, did -- is there any
20 indication of cording, roping, curling, or fraying in
21 Exhibit No. 24?

22 A. No, there's not, but I think that misses the
23 point.

24 The roping --

25 Q. Well, the --

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1 **A. May I finish?**

2 Q. What's your -- what's your opinion based on,
3 then?

4 **A. My opinion is based on what this stuff looks**
5 **like when it comes out.**

6 And these -- these complaints were based
7 on problems that they had with the device during
8 implantation, not what it looked like when it was taken
9 out at explantation. You're confusing apples and
10 oranges in my opinion.

11 Q. Well, I didn't cite the document.

12 **A. Okay.**

13 Q. I am trying to understand.

14 **A. All right.**

15 Q. It says Bard received 197 complaints related to
16 failures of different aspects including connectors,
17 needles, the mesh, et cetera, et cetera.

18 **A. That's exactly what this says.**

19 Q. And it says, "I have reviewed examples of the
20 complaints made by surgeons using Align."

21 Doctor, have you reviewed examples of
22 complaints?

23 **A. I saw some of the complaints verbatim, yes.**

24 Q. And which complaints were those?

25 **A. I can't cite you the name of the surgeon who**

1 sent these things in.

2 I am not sure that I understand your
3 question.

4 Q. Well, they aren't in your binder, Exhibit 11,
5 are they?

6 A. Right. No, they're not in here.

7 Q. And they're not listed on your Reliance List on
8 Exhibit 2 of your report, are they?

9 A. I don't think so.

10 Q. Okay. Well, part of this process is that I get
11 to look at what you reviewed.

12 A. I hear you.

13 MR. POTTS: They're exhibits to
14 Ronald Bracken's deposition.

15 Q. (BY MR. BORANIAN) So, Doctor, are the
16 complaints that you reviewed exhibits to Mr. Bracken's
17 deposition?

18 A. Yes.

19 Q. And do you know how those exhibits were
20 selected?

21 A. No.

22 Q. Do you know who selected them?

23 A. No.

24 Q. Now, 197 complaints from June 2007 to
25 February 2009, do you have any idea, Doctor, how many

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1 devices were actually implanted?

2 A. No.

3 I see the numerator. I do not know the
4 denominator.

5 Q. Okay. I will represent that I don't know
6 either, Doctor.

7 A. Okay.

8 Q. But if it were 5,000 implants during that time,
9 the complaint rate would be something like 3.9 percent,
10 right?

11 A. I will assume your math is correct.

12 Q. And if it were 10,000 implanted during that
13 time, it would be half that, right, about 2 percent,
14 right?

15 A. Right.

16 Q. You didn't review the experience of the other
17 98 percent, did you?

18 A. No.

19 Q. You were looking at those hand selected to an
20 employee in a deposition, right?

21 A. Yes.

22 I would say to you, though, that if you
23 were the patient who had one of these complications
24 occur, the incidence to you, the patient, is 100
25 percent.

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1 Q. I will agree with that.

2 A. Okay.

3 Q. Low complaint rates are a good thing, but that
4 doesn't do much for the one patient with the
5 complication, correct?

6 A. That's correct.

7 Q. I understand that completely, Doctor.

8 But let's talk about the devices that you
9 observed during explants.

10 A. Yes.

11 Q. Those are patients with complications, right?

12 A. Right.

13 Q. So drawing your -- you are not relying on the
14 experience of the, I think it's fair to say, vast
15 majority of women who have had no complications at all,
16 have you?

17 A. If the patient doesn't see me for a complaint,
18 I don't know whether she's having a problem or not, by
19 definition.

20 Q. Right.

21 So you're not considering that patient
22 population?

23 A. Right, right.

24 Q. And have you done any study, respectfully or
25 otherwise, comparing any groups that would help you

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1 determine whether or not cording, roping, fraying, or
2 curling is actually a complication that relates to some
3 defect in the device? That was a bad question. Strike
4 that.

5 **A. I was going to say, that went on and on and on.**

6 Q. You have not done any study on this topic, have
7 you?

8 **A. No, no.**

9 Q. And you haven't reviewed or seen any study on
10 this topic, have you?

11 **A. I did not.**

12 Q. And you didn't review all of the product
13 complaints, did you?

14 **A. No.**

15 Q. Now, you say also in this document that Bard
16 knew internally that Align did not perform well related
17 to curling and cording.

18 And that is based on your reading of Bard
19 documents, right?

20 **A. And based on the depositions from Frytag and**
21 **Bracken.**

22 Q. And these are cited in your report, right?

23 **A. Yes.**

24 Q. But other than those things, there's no other
25 source, right?

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1 **A. Right.**

2 Q. One documents you rely on is this one, Doctor.
3 Let me pull it out.

4 (Reeves Exhibit No. 25 was marked.)

5 Q. (BY MR. BORANIAN) This is Exhibit 25, Doctor,
6 and it's a document that you've cited a number of times
7 in your report.

8 Have you seen this document before?

9 **A. Yes.**

10 Q. You -- you cite a few tests in the report from
11 time to time, including testing with regard to with
12 dimension after relaxing from stated force?

13 **A. Yes.**

14 Q. And let me just ask you, do you know how the
15 analysis was done in preparing this document?

16 **A. No.**

17 Q. Did you try to recreate it in any way?

18 **A. I think I understood it.**

19 They simply take the device and put it in
20 a device that measures the amount of strength that's put
21 on the -- on the tape, and they pull it to see what
22 happens. And you can see it cording right now when I
23 pull on it.

24 Then they start it out first and measure
25 the width of the device, and then they put X amount of

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1 dines of force on it for X amount of time and then
2 remeasure it after looking at it and after testing it to
3 see what happened to the width of the tape.

4 Q. And what you just did there, Doctor, you don't
5 know how much force you're applying there?

6 A. I do not, obviously.

7 Q. And you don't know if -- what you did, you
8 don't know if it simulates during implantation of the
9 device?

10 A. This is my best approximation using my hands.

11 Q. But you've never done it yourself?

12 A. No.

13 Q. So -- so other than what's described in
14 Exhibit No. 25, you haven't reviewed the protocols or
15 other plans that they put together to undertake this
16 testing, have you?

17 A. No.

18 Q. And other than, you know, pulling on it in the
19 way you just demonstrated to us, you haven't tried to
20 recreate these test results, have you?

21 A. I have not.

22 Q. Are you aware, Doctor, of design changes that
23 Bard made to the Teflon shield that goes around the
24 device when it's in the package?

25 A. I know that they had some problems with it

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1 initially. It would not come off and it fit too tightly
2 and they had some instances of the shield breaking when
3 they tried to pull it off.

4 And the concern was that the amount of
5 force that they were going to have to use to pull the
6 sheath off would potentially damage the integrity of
7 the -- of the Align device itself.

8 Q. Had you ever observed that happening, Doctor?

9 A. No, I have not.

10 Q. Has any doctor that you work with ever
11 described that to you?

12 A. Not that I recall.

13 Q. And are you aware of the design changes that
14 Bard made to the shield to address the reports it was
15 receiving?

16 A. I think they were going to try to increase the
17 diameter of the introducer so that there was more room
18 for the sheath and the device to go into the body.

19 Q. And have you evaluated those changes and
20 whether they changed the force required?

21 A. Not -- I don't recall anything about force
22 required.

23 Q. That was a bad question.

24 Have you reviewed -- have you evaluated
25 whether those changes addressed the issue as you're

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1 describing them?

2 A. I remember reading that they were talking about
3 doing it. Whether they, in fact, did it or did not, I
4 don't recall.

5 I think they recognized that there was a
6 problem, and I think that they felt like if they could
7 address it in that regard, they could probably fix it.

8 Q. But you don't know what they did?

9 A. I do not.

10 Q. Did -- any of the surgeons in any of the cases
11 you reviewed for litigation, did any of them describe
12 any difficulty in removing the shield?

13 A. Not that I recall.

14 You mean sheath, not shield?

15 MR. POTTS: You guys have been referring
16 to it as shield.

17 THE WITNESS: Okay. It's a sheath.

18 Q. (BY MR. BORANIAN) Thank you for correcting me,
19 Doctor. I am still on California time.

20 Now, do you know if -- any of the
21 surgeons who implanted the Align device in the patients
22 that you are giving opinions on, do you know in any of
23 them used devices with the old-style sheath versus the
24 new-designed sheath?

25 A. I don't know the answer to that.

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1 Q. Just give me a moment here, Doctor.

2 THE VIDEOGRAPHER: We have about six
3 minutes of tape time left.

4 Q. (BY MR. BORANIAN) This is another document you
5 cited, Doctor, in your report.

6 (Reeves Exhibit No. 26 was marked.)

7 Q. (BY MR. BORANIAN) This is Exhibit 26.

8 A. Okay.

9 Q. Have you seen this document before?

10 A. Yes.

11 Q. This describes manipulation of the sheath
12 itself, correct?

13 A. Right.

14 Q. And whoever did this testing made notes on
15 sheath deformation, correct?

16 A. Right.

17 Q. Does this document speak at all to whether the
18 sheath deformation affected the mesh itself?

19 A. They don't see any evidence that it does.

20 I think the concern that people had,
21 there were a couple of things with regard to the sheath:
22 Number one, there was one patient that I recall in whom
23 the sheath was found -- a portion of the sheath stayed
24 in the patient and was there for the duration that the
25 device was left in place.

1 The other thing that was felt to be
2 problematic was the fact that the sling would take on an
3 unusual, I recall a W shape, and they also talk about a
4 C shape as a result of pulling the sheath off. The
5 shape of the sling changes.

6 And then they say here that they think
7 they may have fixed it.

8 Q. But this document, Exhibit No. 26, does not
9 speak to any deformation of the mesh itself, does it?

10 A. Look at the first paragraph. "Most of the
11 issue appears to be how the sheath curls. If it folds
12 into a simple C shape, the removal is usually relatively
13 easy. If it falls into virtually any other shape, S or
14 W, the forces go up substantially."

15 So they do talk about other shapes.

16 Q. Well, they do, but they don't talk about any
17 shaping of the -- the mesh itself. They talk about the
18 sheath.

19 This document addresses the sheath only,
20 doesn't it?

21 A. Well, the mesh is inside of the sheath.

22 Q. Correct.

23 A. So it -- the -- by definition, if the sheath
24 changes shape, the mesh is going to, too.

25 Q. You've never experienced that yourself?

1 A. By definition, if I have never put one in, I
2 have never seen that, no.

3 Q. So that's an inference you're drawing just from
4 this document?

5 A. Yeah.

6 Q. It doesn't say anything about mesh deformation,
7 does it?

8 A. It says if you've got mesh sitting inside the
9 sheath and if the -- the sheath changes shape and if the
10 mesh is inside it, by definition, the shape of the mesh
11 is going to change, too. I can't foresee that as
12 happening any other way.

13 Q. But that doesn't mean that the mesh will be
14 implanted any other way than flat, does it?

15 A. I don't know what it means.

16 I am not going to make any assumptions,
17 if you altered the shape of the sheath -- to answer your
18 question, I don't think it's clear at all based on this
19 document that you've given me.

20 Q. And the ultimate question, though, is that
21 whatever design changes they made to the sheath, you're
22 not familiar with, right?

23 A. Correct.

24 Q. Let me show you another document that you
25 cited.

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1 (Reeves Exhibit No. 27 was marked.)

2 Q. (BY MR. BORANIAN) This is Exhibit 27. Now,
3 Doctor, I have just a couple of questions on this.

4 You write in your report based on this
5 document that Bard acknowledged that Marlex
6 polypropylene has several negative characteristics. You
7 wrote that on page 15 of your report, if you want to
8 take a look at that. I don't want to rush you.

9 A. Okay.

10 Q. And in the first full paragraph, "Bard
11 acknowledged."

12 You said that, right?

13 A. Uh-huh.

14 Q. Doctor, is there any indication on Exhibit 27
15 that this is a Bard document?

16 A. As you presented this to me, it doesn't say who
17 generated the document.

18 MR. POTTS: Except the Bates stamp at the
19 bottom right-hand corner.

20 MR. BORANIAN: Which is different than
21 the others.

22 A. Avaulta.

23 Q. (BY MR. BORANIAN) The only manufacturer that's
24 highlighted on page 2 of page 27 is Sofradim, right?

25 MR. POTTS: Well, I will represent to you

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1 that this is a Bard document. It was produced in the
2 Bard discovery.

3 MR. BORANIAN: Well, I will not accept
4 that representation. Maybe it's true, maybe it's not.
5 You don't know.

6 MR. POTTS: Well, yes, I do. It's an
7 Avaulta document that we obtained through the Avaulta
8 database.

9 MR. BORANIAN: Unless you can
10 authenticate it as a Bard document, I am not going to
11 accept that representation.

12 Q. (BY MR. BORANIAN) Doctor, you don't know if
13 Bard created this document, do you?

14 MR. POTTS: Bard produced this document
15 in discovery.

16 MR. BORANIAN: There's a question
17 pending.

18 A. I don't know.

19 Q. (BY MR. BORANIAN) Do you know if Sofradim
20 created this document?

21 A. I don't know.

22 Q. In any event, you're attributing Bard's
23 knowledge -- you're making an inference regarding Bard's
24 knowledge based on this document produced in discovery,
25 right?

1 **A. Yes.**

2 Q. Doctor, did you observe anything that you would
3 call curling, roping, cording, or fraying in any of the,
4 I think it's five or six Align patients that you
5 examined for this litigation?

6 **A. Understand that I was not examining these**
7 **patients in the operating room. They were seeing us as**
8 **a patient in on outpatient clinic setting.**

9 And on some of these women, there was a
10 significant degree on vaginal examination of tenderness
11 and scarring. But the only way that I can tell you that
12 I could see fraying, cording, or roping would be to see
13 the exposed sling, and in none of these particular women
14 whom we examined were they examined in the operating
15 room. I don't know whether they were manifesting that
16 or not.

17 That's not a they didn't have it. I am
18 saying to you that in the clinic in an outpatient
19 setting, without being in the operating room, I don't
20 know whether they had those problems or not.

21 Q. Because the nature of your exam didn't permit
22 that, correct?

23 **A. They were not in surgery.**

24 Q. And you didn't look at any explants, if there
25 are any, right?

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1 **A. Correct.**

2 Q. Doctor, let me ask you about the opinion that
3 you stated on page 16 of your report. It's in the
4 heading labeled C. It says, "Bard's mesh" -- forgive
5 me. "Bard's Align mesh is not suitable for its intended
6 application as a permanent prosthetic implant for SUI in
7 the human body because it degrades over time. As a
8 result, it is a defective device and is unreasonably
9 dangerous."

10 Is that what you wrote, Doctor?

11 **A. It says, "design," not, "device."**

12 **But, yes, that's right. That's correct.**

13 Q. So the second sentence is, "As a result, this
14 is a defective design."

15 **A. Yes.**

16 Q. "And is unreasonably dangerous."

17 Is that your opinion, Doctor?

18 **A. Yes, yes.**

19 MR. POTTS: Can we take a break if we're
20 about to hit another major section?

21 MR. BORANIAN: Yes.

22 THE VIDEOGRAPHER: We are off the record.

23 The time is 2:49 p.m.

24 (Recess from 2:49 p.m. to
25 3:00 o'clock p.m.)

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1 THE VIDEOGRAPHER: We are back on the
2 record. The time is 3:00 p.m.

3 Q. (BY MR. BORANIAN) So we were talking about
4 your opinions numbered letter C in your report.

5 Doctor, is that your opinion?

6 A. It is.

7 Q. Let's walk through this, Doctor, so I make sure
8 I fully understand.

9 The first paragraph of section C on page
10 16 speaks about an oxidation process.

11 Is it your opinion, Doctor, that
12 oxidation contributes to the degradation of
13 polypropylene mesh over time?

14 A. It is.

15 Q. And I don't see any citations to anything here.

16 What is the basis for your opinion on
17 that?

18 A. I have articles that I will refer specifically
19 you to if you would like to see this in further detail.

20 I am going to first mention the article
21 by Clave, and this is from the
22 International Urogynecology Journal 2010, volume 21,
23 pages 261 to 270.

24 And I am also going to refer you to the
25 Ostergard articles, and he's got two or three. The

1 first one is from the American College -- it's from the
2 Green Journal of Obstetrics & Gynecology and this is
3 dated October 2010 and it's entitled Polypropylene
4 Vaginal Mesh Grafts in Gynecology.

5 Q. That's one Ostergard article?

6 Is there a second one?

7 A. There is another Ostergard article. Actually,
8 there are two others.

9 They're not all germane to the oxidation
10 process.

11 Q. Okay.

12 A. But the other is a letter he wrote to the
13 International Urogynecology Journal entitled, "Vaginal
14 Mesh Grafts and the Food & Drug Administration," and
15 that is from October 2010, volume 21, pages 1181 to
16 1183, although that doesn't relate to the oxidation
17 issue.

18 And the final one is, Evidence-Based
19 Medicine for Polypropylene Mesh use Compared with Native
20 Tissue Vaginal Prolapse Repair," and this is a comment
21 that he made in Urology 2012, volume 79, pages -- page
22 15.

23 Q. So, Doctor, the Clave 2010 article obviously
24 you're familiar with because it's discussed at some
25 length in the report?

1 **A. Right.**

2 Q. The numerous Ostergard articles and sources
3 that you just cited do not appear in your Reliance List
4 or in your report, Doctor.

5 Did you, or did you not rely on your
6 Ostergard articles in forming your opinion?

7 **A. I did.**

8 Q. Do you understand that I am entitled to know
9 that before we come today to ask you questions?

10 **A. Can I suggest that some of the articles I just**
11 **found within the last couple or three weeks? And I am**
12 **sorry if you don't have them. But if this is an open**
13 **book, you're going to get a copy of it tonight for the**
14 **record.**

15 Q. Okay. Very well.

16 I will note also for the record that the
17 Reliance List is incomplete, and we'll do what we can
18 with that, Doctor.

19 Is there anything else that you wanted to
20 cite regarding the oxidation process? And the reason
21 why I am asking about the oxidation process specifically
22 is because of the paragraph on -- on page 16.

23 When you go onto page 17 of your report,
24 it says, "In addition to the oxidative."

25 So I am just trying to figure out if the

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1 discussion on page 16, is that all there is on
2 oxidation, and then you're moving to something else on
3 page 17?

4 Help me out there, Doctor.

5 A. Well, there -- I did not cite the articles
6 here. I am sorry.

7 Q. So the articles that you just cite, Clave 2010,
8 Ostergard 2010, and the other Ostergard --

9 A. I have also -- Costello is in your list; is it
10 not?

11 Q. Yes, Costello is in there.

12 A. So you have Costello. I am -- I am citing
13 Costello, as well.

14 MR. POTTS: It's Clave. It's cited in
15 here.

16 MR. BORANIAN: I know.

17 Clave is there, sure.

18 MR. POTTS: What's missing?

19 MR. BORANIAN: Ostergard.

20 MR. POTTS: Well, there's two Ostergard
21 in the list; is that right?

22 MR. BORANIAN: No. There's just one, and
23 neither is them is not one of the ones he just said.

24 MR. POTTS: There's two, right?

25 MR. BORANIAN: No.

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1 MR. POTTS: So you added how many more
2 Ostergards?

3 THE WITNESS: Two.

4 MR. POTTS: Okay.

5 THE WITNESS: And I think I said you and
6 I called these out, that neither of those related to the
7 oxidation process. It's just the one article from
8 Obstetrics & Gynecology.

9 The Urology article and the
10 International Urogynecology Journal don't relate to the
11 oxidation process.

12 Q. (BY MR. BORANIAN) Do the Ostergard articles
13 that you're telling us about now appear on your list,
14 Exhibit 10?

15 A. Yes.

16 Q. Okay. That's helpful. Thank you, Doctor.

17 A. You're welcome.

18 Q. Let me ask you about the articles that you do
19 cite, Doctor.

20 A. All right.

21 Q. You say on page 17 of your report that
22 peer-reviewed literature regarding degradation/oxidation
23 of polypropylene in the human body dates back to the
24 1960s and has been reported in numerous such
25 publications.

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1 That's what you wrote there, right?

2 **A. Right.**

3 Q. And take a look at the three articles that you
4 cite there in support. I can show them to you.

5 **A. I have them right here: Clave, Costello, and**
6 **Ostergard.**

7 Q. I have Liebert, Williams, and Oswald.

8 Let me mark those.

9 **A. All right.**

10 (Reeves Exhibit No. 28 was marked.)

11 Q. (BY MR. BORANIAN) So this is the Liebert
12 article, Exhibit 28. And Exhibit 28 is Liebert 1976,
13 "Subcutaneous Implants of Polypropylene Filaments."

14 And this is a study in hamsters, not
15 humans, correct?

16 **A. Correct.**

17 Q. So what I am trying to understand here, Doctor,
18 when you say that peer-reviewed literature regarding
19 degradation/oxidation in the human body dates back to
20 1960s, the Liebert article is not a human study, is it?

21 **A. No, it's not.**

22 Q. And, in fact, Liebert with the hamster study,
23 that compared polypropylene without stabilizers to
24 polypropylene with an FDA-approved stabilizer, right?

25 **A. Right.**

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1 Q. And Dr. Liebert and his colleagues found no
2 change in the polypropylene with stabilizers; is that
3 right?

4 A. Uh-huh.

5 Q. Do you know, Doctor, what the formulation is
6 for the polypropylene is that goes into the Align mesh?

7 A. Can I cite you the chemical formulation of it?
8 Is that what you're asking?

9 Q. Yes.

10 A. No, I can't do that.

11 Q. You can't do that.

12 Do you know if it contains antioxidants?

13 A. Yes. I don't -- I don't know the answer to
14 that.

15 Q. So the second article that you cite here is
16 from Dr. Williams.

17 (Reeves Exhibit No. 29 was marked.)

18 Q. (BY MR. BORANIAN) We'll call this Exhibit 29,
19 Doctor.

20 A. Okay.

21 Q. Exhibit 29 is DF Williams 1982, "Review
22 Biodegradation of Surgical Polymers."

23 Now, Doctor, this -- and this is another
24 article that you're citing in support of the idea that
25 peer-reviewed literature regarding degradation in the

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1 human body dates back to the 1960s, right?

2 **A. Uh-huh.**

3 Q. There is no human data reported in this review,
4 is there?

5 **A. He's talking -- no.**

6 **There's some rat data in here.**

7 Q. Okay.

8 **A. And he's talking about studies of bacteria and**
9 **what bacteria contributes to the mix.**

10 Q. So he is reviewing polypropylene data in
11 hamsters, right?

12 **A. Uh-huh.**

13 Q. And he's also generating hypotheses about
14 degradation, right?

15 **A. Yes.**

16 Q. And, in fact, he says in --

17 **A. Where are you reading? Excuse me.**

18 Q. That was rude of me. Page 1237.

19 He says there's a certain attractiveness
20 in the hypothesis of enzyme-accelerated in vivo polymer
21 degradation, since enzymes have a characteristic ability
22 to catalyse certain chemical reactions.

23 He goes on to say lower in the paragraph,
24 "There are some difficulties involved in confirming the
25 hypothesis. However, since enzymes are normally so

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1 substrate specific and one does not normally associate
2 their catalytic effect with synthetic high
3 molecular-weight polymers. Nevertheless, it remains and
4 attractive possibility, worthy of further
5 investigation."

6 So this is hypothesis generating,
7 correct?

8 **A. This is a review article.**

9 **This is not a report of anything that was**
10 **done. It's a review.**

11 Q. So he's suggesting here an area of further
12 investigation?

13 **A. He is.**

14 Q. He's not drawing a conclusion?

15 **A. He is not.**

16 Q. And, in fact, he categorizes the different
17 polymers on page 1234 at the very bottom. He says,
18 "Thus, polymers can be placed in a ranking order of
19 predicted susceptibility to in vivo degradation in the
20 sequence: Hydrophobic, comma, no hydrolyzable bonds -
21 most stable."

22 That's what he says, right?

23 **A. That's what he says.**

24 Q. And polypropylene is a hydrophobic polymer with
25 no hydrolyzable bonds, correct?

1 Is that correct?

2 A. Are you reading that from somewhere, or are you
3 telling me that from your knowledge?

4 Where do you see that?

5 Q. That's actually in this article under No. 3 on
6 page 1234 in the second column.

7 It talks about in vivo degradation of no
8 hydrolyzable polymers, right?

9 A. Okay.

10 Q. And that includes what, Doctor?

11 A. Polyolefins, polyethylene, and polypropylene.
12 Yes. Okay.

13 Q. So according to Dr. Williams' review -- and
14 this is back in 1982 -- polypropylene is in the group of
15 polymers that is the most stable in vivo, correct?

16 A. That is correct.

17 I would point out that that is not
18 collaborated in humans in the Clave article or in the
19 Ostergard article. So while this may be the case when
20 he wrote this paper in 1982, you're citing the
21 information that is now 18 plus 14 -- 32 years old.

22 Q. Well, in fairness, Doctor, you cited it to me.

23 A. Okay.

24 Q. And you cited it in support of the proposition
25 that there was literature regarding degradation of --

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1 **A. All right.**

2 Q. That's not the case with this article, is it?

3 **A. Correct. All right.**

4 Q. The next article that you cite in that footnote
5 is Oswald and Turi.

6 That's a well-known study, isn't it?

7 **A. I don't know how well-known it is.**

8 Q. I thought it was. Let me show it to you.

9 (Reeves Exhibit No. 30 was marked.)

10 Q. (BY MR. BORANIAN) This is the Oswald article,
11 Doctor. It's Exhibit No. 30.

12 And this, again, is not a study of
13 polypropylene or living tissue, is it?

14 **A. No.**

15 Q. In fact, he's studying degradation in glass
16 containers in response to oxygen and argon, right?

17 **A. Right.**

18 Q. And he's measured that at temperatures of 75
19 degrees centigrade, 100 degrees, 120 degrees, and 140
20 degrees, right?

21 **A. Right.**

22 Q. The body temperature is 37 degrees centigrade,
23 right?

24 **A. Right.**

25 Q. So this is not only in glass containers?

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1 It doesn't approximate in any way the
2 environment in the human body, right?

3 **A. It does not.**

4 Q. So those are the three articles that you cite
5 in your footnote 7.

6 But you can agree that none of those
7 speak to degradation in the human body, correct?

8 **A. Correct.**

9 Q. Did you prepare this part of your report,
10 Doctor?

11 **A. I did not write that paragraph per se.**

12 I did this -- as I said to you earlier,
13 this was a collaborative effort, and I do not recognize
14 my verbiage in that particular paragraph.

15 Q. So someone from the Potts Firm maybe put that
16 in there?

17 **A. May have.**

18 Q. But in any event, you signed the report, right?

19 **A. I signed the report.**

20 Q. So let's talk about articles that you discussed
21 a little more here. Let's talk about Costello.

22 **A. Okay.**

23 (Reeves Exhibit No. 31 was marked.)

24 Q. (BY MR. BORANIAN) Do you got it there, Doctor,
25 as Exhibit 31?

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1 **A. Yeah.**

2 **I have got it marked, as well.**

3 Q. Uh-huh. Now, Costello -- and for the record,
4 Exhibit 31 is Costello 19 -- 2007, "Characterization of
5 Heavyweight and Lightweight Polypropylene Prosthetic
6 Mesh Explants from a Single Patient," correct?

7 **A. Correct.**

8 Q. So this is a -- a one-patient Case Report where
9 they removed two samples of two -- of one mesh and one
10 sample of another mesh from one patient, correct?

11 **A. Correct.**

12 Q. Now, the samples were of a composite mesh,
13 right?

14 **A. Right.**

15 Q. So, first of all, this does not involve any
16 treatment for pelvic issues, right?

17 **A. I think this was a hernia repair.**

18 Q. Which makes sense, because the composite mesh
19 was a hernia repair product, correct?

20 **A. Correct.**

21 Q. And that's a composite product made of
22 polypropylene named ePTFE, right?

23 **A. Right.**

24 Q. And ePTFE, that's like the superslick, super
25 microporous mesh -- it's a product like cortex, right?

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1 **A. Correct.**

2 Q. And the reason why it's used in hernia's is
3 because it doesn't stick to anything, right?

4 **A. That's the intent.**

5 Q. Do you know the properties of the composite
6 mesh that were explanted from the Costello patient in
7 terms of pore size?

8 **A. I do not.**

9 Q. And then there was also a lightweight
10 polypropylene mesh, correct?

11 **A. Right.**

12 Q. Now, what Dr. Costello concluded was that he
13 observed some changes in the heavy -- what he's called
14 the heavyweight polypropylene ePTFE composite mesh,
15 right?

16 **A. Yeah.**

17 He concludes in the last paragraph in his
18 abstract at the top of page 168 is the hypothesis was
19 that heavyweight polypropylene would insight a more
20 intense inflammatory response that lightweight
21 polypropylene and, thus, undergo greater oxidative
22 degradation. Overall, the results support this theory.

23 That's what he says.

24 Q. Okay. He did not observe -- well, that's his
25 conclusion.

1 But what he observed was what he called
2 degradation in the composite mesh, right?

3 A. Right.

4 Q. And, in fact, what he's characterized in the
5 SEM analysis on page 172, he said that, however,
6 micro-grafts of both heavyweight polypropylene of the
7 explant composite mesh revealed micro-cracks in a
8 transverse direction, as well as peeling of the top
9 layer of the fibers.

10 Is that what it says?

11 A. You're reading the last paragraph.

12 Based on his scanning electron
13 microscopy, yes.

14 Q. Was there any other evidence of degradation
15 other than the SEM?

16 A. Well, he's got histology on it, as well.

17 Q. And what did he find?

18 A. He says -- well -- let's see if he describes
19 his histology.

20 He shows electron microscopy pristine
21 before it's implanted. I am assuming that's something
22 he got from the manufacturer showing what it was like
23 before it was implanted.

24 And then the second picture on page 173
25 is something that came out of a patient having been

1 there for an additional 5 months compared to a specimen.
2 So he's showing preimplantation and postimplantation
3 mesh on the pictures on page 173.

4 And then the histology is reported on
5 page 174. "Review of the H&E stained specimens revealed
6 multinucleated giant cells in all three specimens
7 indicative of a foreign-body reaction. All three
8 specimens also demonstrated an inflammatory response.
9 The cell types in specimens 1 and 2 were indicative of
10 chronic inflammation with large populations of
11 macrophages and lymphocytes. The third specimen
12 demonstrated an inflammatory response with many
13 neutrophils consistent with acute inflammation.

14 So there was more than just scanning
15 electron microscopy.

16 Q. Okay.

17 A. There was histology, as well.

18 Q. Are you relying on his findings in connection
19 with that composite mesh in forming your opinion that
20 polypropylene degrades in the mesh?

21 A. I am relying on this for what he says it's for.

22 I am relying on what he says about the
23 mesh that he took out. I am not extrapolating from this
24 anything.

25 Q. It's -- it's a Case Report, right?

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1 **A. Right.**

2 Q. So it's not a study of degradation in
3 population?

4 It's just a report on one patient, right?

5 **A. But I have no reason to assume that this is not**
6 **a valid observation. That's what you're asking me.**

7 Q. No.

8 **A. Now, did he have a thousand patients in this**
9 **study? No. It's a Case Report of one.**

10 Q. That was my question. Thank you, Doctor.

11 **A. And the answer is, yes, it's a Case Report of**
12 **one.**

13 Q. And you're relying on that Case Report to form
14 your opinions, right?

15 **A. Of course.**

16 Q. And he observed no changes or fewer changes in
17 the lightweight polypropylene, correct?

18 **A. Correct.**

19 Q. So it's not the propylene that's degrading, is
20 it, because it's not degrading when it's presented in a
21 different form?

22 **A. Can you explain what you by, "presented in a**
23 **different form"?**

24 Q. Sure.

25 Your opinion is that polypropylene

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1 degrades in the body, correct?

2 **A. Correct.**

3 Q. And here you have an observation in one patient
4 of one product for which Dr. Costello has reported signs
5 of degradation made of partly polypropylene, and you
6 have his observations of another product made entirely
7 of polypropylene that has not shown degradation.

8 So how does this article support your
9 opinion that polypropylene degrades in vivo?

10 **A. It's not his; it's the only article, as well.**

11 **But I think this is pretty conclusive. I**
12 **am sorry you don't see it like that.**

13 Q. Well, do you know the properties of the
14 lightweight mesh that was explanted from the patient?

15 **A. No.**

16 Q. Do you know the properties of the Align mesh?

17 **A. In terms of?**

18 Q. In terms of the pore size, the weight, the
19 fiber diameter.

20 **A. Yeah. We've got that.**

21 **The pore size is documented in one of the**
22 **documents that I have. It's in the Bracken deposition,**
23 **if I am recalling correctly.**

24 **The pore size is documented also in my**
25 **report.**

1 Q. Do you know what the pore size is, Doctor?

2 A. Not off the top of my head. I can't cite you
3 the numbers, but I can -- I can get to it, if you give
4 me a second.

5 Q. So let's take a look at Exhibit 25. That is
6 the Design Qualification and Competitive Product Testing
7 document.

8 A. I have got that.

9 What page?

10 Q. This is -- I am on page -- well, it's -- using
11 the documents -- we'll use the Bates number 7292.

12 A. Okay.

13 Q. And this is the result of the visual inspection
14 of the Align mesh, Uretex mesh, TVT, Obtryx, and Monarc,
15 right?

16 A. I am seeing that, yes.

17 Q. Okay. So you understand that the Align mesh --
18 well, let's just take a look.

19 Pore size is in inches, right, on the
20 chart there?

21 A. Yeah.

22 It says -- I don't see where it's
23 saying -- yeah. It says fiber diameter in inches, and
24 pore sizes. I see it.

25 Q. In inches?

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1 **A. Right.**

2 Q. Okay. So I will pull out my cheat sheet
3 document, if you don't mind.

4 **A. You don't have all those numbers in your head?**

5 Q. I don't convert inches to millimeters in my
6 head.

7 **A. All right.**

8 Q. So -- so the dimensions -- the fiber diameter
9 in Align is .0047 inches, right, which would be about .1
10 millimeters?

11 Is that right, Doctor?

12 **A. I think -- if your math is right, I am agreeing**
13 **with you, yes.**

14 Q. And the pore size for the large pore in the
15 Align is on the -- the pore length/height on average is
16 .048 inches, right, Doctor?

17 **A. Right.**

18 Q. And that converts to about 1.2 millimeters,
19 correct? I think it's exactly 1.2 millimeters.

20 **A. Okay.**

21 Q. And then the large pore width going in that
22 same column onto the next page is .039 inches, and that
23 converts to 1 millimeter.

24 Correct, Doctor?

25 **A. Okay.**

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1 Q. So the fiber diameter is .1 millimeters. The
2 pore size is 1 millimeter by 1.2 millimeters.

3 Can we agree on that, Doctor?

4 A. Yes.

5 Q. And I think it's been represented in this
6 litigation and elsewhere that the pore size in the Align
7 mesh at the center is generally considered to be 1.2
8 millimeters.

9 Would you agree with me?

10 A. Yes.

11 Q. So you would agree with me that the pore size
12 is 1.3 millimeter?

13 A. Yes.

14 MR. POTTS: And once again, there's two
15 different pores. There's large and small.

16 MR. BORANIAN: At the center, the pores
17 at the center of the mesh.

18 MR. POTTS: Is that the large or the
19 small?

20 MR. BORANIAN: The large.

21 Q. (BY MR. BORANIAN) So going back to the
22 Costello article, Doctor, do you know the pore size of
23 the composite mesh that was explanted from this patient?

24 A. No.

25 Q. And do you know the pore size of the

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1 lightweight polypropylene mesh that was explanted?

2 A. No.

3 Q. Can you tell, Doctor, with your knowledge
4 sitting here today whether the Align mesh is more like
5 the lightweight mesh that showed no degradation, or is
6 it more like the composite mesh that showed some
7 degradation?

8 A. I think it's more like -- I think it's more
9 like the mesh that did show degradation.

10 Q. And why do you say that, Doctor?

11 A. Because of pore size.

12 But again, we don't have basis for
13 comparison here. I am just telling you that one of the
14 major problems with the Align product is the fact that
15 the pore size is too small, and that's what has led to
16 such a huge problem with the scarring that they've had
17 with it and the fact that they've had erosions of the
18 mesh, and that they've had problems with it.

19 It's a relatively large-pore mesh and
20 they relate to that and they're talking about
21 potentially changing the product to make the mesh size
22 larger.

23 Q. Well, we'll get into pore size in a --

24 A. At another time, okay.

25 Q. I am still with Costello. We'll go on to Clave

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1 in a couple of minutes.

2 We just don't know what the appropriate
3 comparator is for Dr. Costello?

4 We don't know if the Align is more like
5 the composite mesh which is partly composite and
6 described as heavyweight versus the lightweight mesh?

7 **A. No.**

8 Q. We just don't know, do we?

9 **A. No.**

10 Q. Let's take a look at the Clave article that you
11 have cited and relied upon in your report. We'll mark
12 this as Exhibit 32, but you have a marked copy.

13 **A. I have a well-marked copy.**

14 (Reeves Exhibit No. 32 was marked.)

15 Q. (BY MR. BORANIAN) Exhibit 32 is Clave 2010,
16 "Polypropylene as Reinforcement in Pelvic Surgery is not
17 Inert," right, Doctor?

18 **A. Right.**

19 Q. Let's take a look first at some of the data
20 that Dr. Clave reports.

21 First he says on the -- on page 262, he
22 says, "Usually mesh material with a surface density
23 below" --

24 **A. Excuse me.**

25 **Where are you reading specifically?**

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1 Q. I am sorry.

2 The bottom of the second paragraph of
3 262. It says, "Usually mesh material."

4 Do you see that?

5 A. Oh, yeah. I am with you.

6 Q. "Usually mesh material with surface density
7 below 50 to 60 grams percent meter squared and/or pores
8 larger than 1.3 millimeters are considered low weight
9 and/or high porosity."

10 So by Dr. Clave's measurements, the Align
11 mesh considered low weight and/or high porosity,
12 correct?

13 A. According to this definition, yes.

14 Q. So he has included meshes meeting that
15 definition in his group that he's calling LDPPMF, right,
16 which is --

17 A. Low-density polypropylene.

18 What's the, "MF," stand for?

19 Q. Monofilament.

20 A. Monofilament, yes.

21 Q. And we agree that the Align mesh is a
22 monofilament?

23 A. Yes, we are.

24 Q. So take a look at the data reports in table 1.

25 A. Okay.

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1 Q. He reports in -- this, Doctor, is a study of 84
2 explanted meshes, correct?

3 A. He talks about 100 patients and 84 meshes, yes.

4 Q. So table 1 tells us that of those 84 explants,
5 73 were polypropylene, right?

6 A. That number is not added up here.

7 Did you add it up to get that 73?

8 Q. I have PPMF and --

9 A. 73.

10 I am with you, okay. Yes.

11 Q. And then composite polypropylene is 8?

12 A. Right.

13 Q. And then PET is 13?

14 A. Right.

15 Q. So we have 73 polypropylene meshes.

16 And of that, we have 28 that are of the
17 low-density polypropylene monofilament like the Align
18 mesh?

19 A. Right.

20 Q. So he reports then in table -- well, it's not
21 numbered, but it's at the top of page 264.

22 A. That's the same chart.

23 What are you --

24 Q. 266. Sorry, Doctor. Thank you.

25 So of the polypropylene meshes that were

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1 explanted, this table shows which were deteriorated and
2 which were non-deteriorated.

3 And of the low-density polypropylene
4 monofilament, he shows 6 deteriorated and 22
5 non-deteriorated, 40 percent of degradation at 21.43
6 percent, correct?

7 **A. Correct.**

8 Q. So of the 84 explants -- of the 100 patients
9 and then the 84 explants and of the 28 low-density
10 polypropylene monofilaments, he showed 6 that showed
11 degradation, correct?

12 **A. Correct, correct.**

13 Q. And you wrote in your report here that -- in
14 the middle of page 18, "The heavyweight meshes showed
15 even greater cracking."

16 Do you see that in the middle in the
17 discussion of Clave, the heavyweight meshes?

18 **A. Yes.**

19 Q. "The heavyweight meshes showed greater cracking
20 than the lower-density meshes. According to Dr. Clave,
21 all of the polypropylene explants, 84, showed some
22 degradation."

23 That's not an accurate representation of
24 the article, is it?

25 **A. He -- No, that's not.**

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1 He said that some 22 of these were not
2 non-deteriorated.

3 Q. I think I understand the error.

4 He does say that he observed degradation
5 in all types of polypropylene?

6 A. Correct.

7 Q. But he didn't say he observed it in all of the
8 explants, did he?

9 A. And I think we're also talking about
10 deterioration versus degradation.

11 Q. And what's the difference, Doctor?

12 A. This may be the -- we're splitting hairs, but I
13 think if there is degradation, then there's been change.

14 If there's deterioration, I would
15 interpret that as being a more deleterious process with
16 cracking and with breakdown of the product.

17 Q. Okay. Well, he doesn't seem to be drawing much
18 of a distinction.

19 If you look at the top of page 266, he
20 says deteriorated, 6; non-deteriorated, 22. Percentage
21 of degradation, 21.43.

22 Do Dr. Clave --

23 A. You think --

24 Q. I can't read his mind, but that's what he's
25 written there.

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1 In any even, he's reporting a 21.43
2 percent rate of degradation in the type of mesh that the
3 Align mesh is, right?

4 A. Yeah.

5 And I think --

6 Q. And that would be conversely at 79.57 percent
7 rate of non-degradation in that type of mesh, right?

8 A. I guess he was -- okay. I see what you're
9 saying.

10 Yes.

11 Q. And you say in the next sentence of your report
12 numbered page 18 that oxidation of the implanted mesh
13 due to free-radical attack through the synthesis of
14 peroxide and so on was listed as just one potential
15 cause of the oxidative degradation within the
16 septic environment.

17 Dr. Clave doesn't use the term, "septic
18 environment," does he?

19 A. I don't recall seeing that there.

20 The person who uses and thinks and talks
21 in terms -- who talks in those terms is Ostergard. And
22 he talks about the fact that the vagina is a clean
23 contaminated space.

24 Q. Okay.

25 A. And we can't make that sterile.

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1 Q. Well, if you look at the bottom of page 266,
2 the very last paragraph, Dr. Clave is talking about
3 several hypotheses concerning the degradation of the
4 polypropylene are described below.

5 That's what he says?

6 A. Right.

7 Q. So he's describing hypotheses here?

8 A. Right.

9 Q. These are not conclusions that he's drawn,
10 correct?

11 A. He says, "None of these, particularly direct
12 oxidation, could be confirmed in this study."

13 Q. And that includes oxidation due to free-radical
14 attack, right?

15 A. Right.

16 Excuse me, if I may. I want to go to
17 page 267 in the same article.

18 Q. Sure.

19 A. "This hypothesis may explain the observed
20 degradation occurring only for specimens implanted
21 beyond three months. This time would correspond to the
22 necessary period for oxidation to affect the
23 polypropylene structure."

24 So it -- I think what I hear him saying
25 here is that the longer this stuff remains in place, the

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1 **greater the potential for oxidation to occur.**

2 Q. But he still observed the lowest incidence of
3 oxidation in low-density polypropylene monofilament,
4 right?

5 **A. That's right.**

6 Q. And he still has said that he hasn't actually
7 confirmed any of these hypotheses?

8 **A. That's correct.**

9 Q. Now, he did -- it looks like three kinds of
10 tests: FTIR, SEM, and DSC.

11 What does, "DSC," mean, Doctor?
12 Differential scanning calcimetry, correct?

13 **A. Yeah. Correct.**

14 **That's a heat test.**

15 Q. Now, he did not find any evidence of
16 degradation with the DSC test; is that true?

17 **A. In this study, there's no differences between**
18 **DSC thermograms between pristine and degraded samples**
19 **was found.**

20 Q. And he didn't find any differences in the FTIR
21 test?

22 They were inconclusive, right?

23 **A. To quote his last sentence, "Additionally, FTIR**
24 **analysis did not conclusively confirm that the**
25 **degradation was due to oxidation."**

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1 Q. So Clave's hypothesis about the degradation is
2 based on his SEM observations, right?

3 A. And his his -- excuse me -- and the histology
4 that he did.

5 Q. Well, that was Costello when he talks about
6 histology.

7 A. I am sorry. Okay. I am sorry, I am sorry.
8 He didn't do any histology.

9 Q. So when you look at SEM, it's a superstrong
10 microscopic image of the mesh, right?

11 A. I know what that is.

12 Yes. Right.

13 Q. For the benefit of the jury --

14 A. Scanning electron microscopy.

15 Q. I know you know what that is.

16 A. Okay. All right.

17 Q. Now, before he scanned the meshes with SEM,
18 Dr. Clave treated the meshes with formalin and gluteal
19 formaldehyde, right?

20 A. Yes.

21 Q. Would you agree that those chemicals would
22 result in hardening of the mesh?

23 A. He's got to fix the mesh so that he can look at
24 it with the scanning electron microscope. What effect
25 those particular products had on the mesh, I wouldn't

1 presume to know.

2 I will put it to you like this: It's got
3 to be fixed. I would call these fixatives for electron
4 microscopy.

5 What effect they would have on the mesh
6 per se, I am not -- I don't know.

7 Q. Okay. I think I understand that.

8 Would it also have an effect on any
9 proteins that were on the mesh?

10 A. I don't know.

11 Q. Would it harden the proteins?

12 A. I don't know.

13 Q. Now, polypropylene, we have established, is a
14 hydrophobic polymer?

15 A. Yes.

16 Q. Now, PET is hydrophilic, right?

17 A. Uh-huh.

18 Q. Now, Doctor, you tell me, would animal proteins
19 stick to material that is hydrophilic?

20 A. I don't remember. I don't know.

21 Probably not.

22 Q. Is it possible --

23 A. Probably not, if I had to bet.

24 Q. Is it possible that animal proteins would stick
25 to hydrophilic polymers?

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1 A. Well, you're asking me two separate questions.
2 So if I say yes to one, I have got to say not to the
3 other.

4 Q. Well, they were two separate questions.

5 A. Yeah.

6 Q. But I don't understand your answer.

7 A. Well, repeat the question, and let me try
8 again.

9 Q. The first question was, do animal proteins
10 stick to hydrophobic polymers?

11 And the second question is, it possible
12 that animal proteins stick to hydrophobic polymers?

13 A. I don't think they probably do on a routine
14 basis.

15 Could they? Is it possible? I guess
16 it's possible.

17 Q. So if animal proteins had stuck to hydrophobic
18 polymers such as polypropylene, would you expect to see
19 that under SEM electron microscopy?

20 A. I don't know.

21 Q. Now, how about PET?

22 A. I don't know.

23 Q. Do animal proteins stick to PET?

24 A. I don't know.

25 You're -- you're beyond my pay grade with

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1 **that question.**

2 Q. So you don't do -- that's not part of your
3 practice, doing testing of polymers, right?

4 A. No.

5 Q. Did you do any microscopy as part of your
6 practice?

7 A. I -- you know, I would look at -- when I would
8 take out tissue, when we were concerned about the
9 possibility of cervical cancer and I was doing a
10 procedure called a cervical conization and we would send
11 that tissue down -- or if I was doing an endometrial
12 biopsy or a D&C looking for malignancy, I would go down
13 to the pathology laboratory and look at the frozen
14 section under the microscope with the pathologist so I
15 could see what he was seeing.

16 But in terms of me doing any scanning
17 electron microscopy, the answer is no.

18 Q. So the kinds of analysis that Dr. Clave is
19 doing here, that's not within your area of expertise?

20 A. Absolutely not.

21 Q. So based on SEM photographs that are included
22 in the article, is it possible to tell if there is any
23 effect on the fibers beyond the surface-level cracks
24 that we see?

25 A. He shows what he calls to be intact and

1 degraded types of product that was removed in these
2 surgical cases, and he shows some of these have -- more
3 have experienced more degradation than others.

4 And just looking at these visually, the
5 least amount of degradation appears to have occurred in
6 the low-density product. Looking down the page, the
7 next amount seems to be higher in the high-density
8 product. And in the monofilament, it's highest.

9 Q. So he observed the least effect on the
10 low-density product, right?

11 A. Yes.

12 And then he makes the conclusion on page
13 268, "Polypropylene, in particular low-density
14 polypropylene monofilament, is the most-used material in
15 the PFD surgery," pelvic floor -- he uses too
16 many abbreviations -- pelvic floor disorder surgery.

17 "It is generally considered an inert
18 material. This study contradicts this established fact
19 and confirms the results of other studies on
20 polypropylene materials used in other areas of medical
21 specialization."

22 So I think his conclusion is what we've
23 got to go with here.

24 Q. Well, and I think we have to go with what his
25 data shows, Doctor.

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1 And his data shows that -- doesn't it,
2 that in nearly 80 percent of the low-density meshes, he
3 showed no degradation at all?

4 **A. That's not what he concluded.**

5 MR. POTTS: Objection; vague.

6 **A. And I am reading that from page 268.**

7 Q. (BY MR. BORANIAN) I see where you're reading,
8 Doctor.

9 **A. Okay.**

10 Q. But my question is, there was no degradation at
11 all in 80 percent of the low-density materials, right?

12 **A. Well, he says it's generally considered that**
13 **it's inert, and he says this contradicts that**
14 **established fact.**

15 Q. So he was not able to explain in any way why he
16 saw degradation in some samples and not in others?

17 **A. I don't think he was.**

18 He was just reporting what he saw. He --
19 **he was giving you possible reasons.**

20 Q. And did he suggest in his article anywhere --

21 **A. By the way, may I -- excuse me. Go ahead.**

22 Q. I'll go first.

23 -- that the degradation that he observed,
24 especially that in the low-density materials, had any
25 clinical significance at all?

1 A. No.

2 I want to -- I am sorry.

3 What I wanted to tell you is on page 269,
4 there is the phrase, "septic environment."

5 Another explanation concerns radical
6 oxidation due to the, quote, septic environment. That's
7 where that phrase came from. I knew I had seen that
8 somewhere in this article, okay?

9 Q. Great. Thank you.

10 Now, let me show you an article by
11 Dr. Detayrac.

12 (Reeves Exhibit No. 33 was marked.)

13 Q. (BY MR. BORANIAN) Exhibit 33 is de Tayrac,
14 d-e, T-a-y-r-a-c.

15 A. Okay. I have another one by him, the same
16 author, but a different study.

17 Go with yours first.

18 Q. Let me tell the court reporter what this is.

19 It's a 2011, and it's called, "Basic
20 Science and Clinical Aspects of Mesh Infection in Pelvic
21 Floor Reconstructive Surgery."

22 And I don't think I saw a de Tayrac
23 article on your list, Doctor.

24 Where were you looking?

25 A. Well, it's the fifth one from the bottom of my

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1 list, and it's under --

2 Q. I understand.

3 A. Do you see it? I didn't put the, "D-e," in
4 front of it.

5 Q. Okay. Very well.

6 A. Okay.

7 Q. So Dr. de Tayrac, if you look at page 778,
8 tried to duplicate Dr. Clave's analysis. And what he
9 wrote was, "Using the same model of mesh infection, we
10 also experimentally tested Clave's conclusion regarding
11 a correlation between infection and polypropylene
12 degradation. Polypropylene meshes were implanted in the
13 incisional abdominal hernia model in Wistar rats and
14 inoculated with 10 to the 6th power of E. coli as
15 described previously. After 30 days, the meshes were
16 explanted and washed with DMSO and ultrasonic shock,
17 then examined by environmental scanning electron
18 microscope, ESEM. At the same time, polypropylene
19 meshes were inoculated in vitro with the same isolate E.
20 coli, then explanted and washed with the same process.
21 In this study, we also observed signs of superficial
22 degradation and transverse cracks, but this appeared to
23 concern only the biofilm, with no effect on the implant
24 thread itself."

25 That's what de Tayrac concluded, right?

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1 **A. That's what it says.**

2 Q. And if you look at pages that he has cited --
3 he has included above -- this shows the polypropylene
4 fiber with some sort of film on it.

5 But then when they washed it in letter C
6 there, it's a pristine fiber, right?

7 **A. In picture C, it is.**

8 Q. And did Dr. Clave in his article take into
9 account the possibility of what he was observing was
10 surface film and not actually degradation of the fibers?

11 MR. POTTS: Objection; calls for
12 speculation.

13 Go ahead.

14 **A. Clave didn't specifically address that issue.**

15 Q. (BY MR. BORANIAN) And Dr. Clave observed only
16 surface-level oxidation, right?

17 **A. I think so.**

18 Q. And it could have been a biofilm or a film he
19 was observing, right?

20 **A. I am not sure what he was observing. I don't**
21 **know.**

22 Q. Now, you have some opinions in your report,
23 Doctor, about Bard's reaction and treatment of the Clave
24 article.

25 Let me ask you, do you know anything

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1 about that beyond the documents that you cited in your
2 report?

3 **A. The only access that I -- the only thing I know**
4 **about that is what I read in the depositions.**

5 Q. And in the documents that were produced in
6 discovery, right?

7 **A. Yes.**

8 Q. And did you draft that portion of your report?

9 **A. Show me specifically where you're talking**
10 **about.**

11 Q. Starting where we left off after Clave. It
12 says, "Bard was clearly aware of the Clave article."

13 There, you're not citing a deposition?
14 You're citing a document produced in discovery?

15 **A. Yes, yes. And I saw that.**

16 Q. Now, did you prepare this portion of your
17 report?

18 MR. POTTS: Let him read it.

19 Read through it.

20 When you say, "this portion," are you
21 referring to everything that remains in the section, or
22 what?

23 MR. BORANIAN: That's a good question.
24 That's a good objection.

25 MR. POTTS: There's four or five pages.

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1 MR. BORANIAN: I am referring to
2 everything up to letter D.

3 MR. POTTS: Okay. And the question is
4 did he --

5 Q. (BY MR. BORANIAN) Did you prepare this?

6 MR. POTTS: I think he testified he
7 prepared the report in collaboration with the
8 plaintiffs.

9 A. Yeah.

10 **This was a collaborative effort.**

11 Q. (BY MR. BORANIAN) Okay.

12 A. **This -- this is a collaborative effort.**

13 Q. Okay. And you are citing here throughout --
14 well, I don't see any citations to deposition testimony,
15 so it must be all based on the Bard documents, right,
16 Doctor?

17 A. Yes.

18 **And this was also discussed in the -- I**
19 **think the Bracken deposition, if I recall, or the Frytag**
20 **deposition.**

21 Q. So just for an example, the very first
22 sentence, "Bard was clearly aware of the Clave article,"
23 you're drawing that conclusion based on the Bard
24 documents, right?

25 A. Yes.

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1 Q. So do you know whether Bard conducted stability
2 testing on its polypropylene mesh?

3 A. I don't know the answer to that question.

4 Q. Did you ask to see any of these stability
5 testings that might have occurred?

6 A. I did not.

7 Q. Do you know whether Bard reviewed data from
8 the, you know, 50 years of use of polypropylene in
9 permanent surgical implants?

10 Do you know if Bard reviewed that data?

11 A. I don't know.

12 Q. At the very end of this section, Doctor, you
13 give an opinion in the last paragraph of section C.

14 A. You're on page? Excuse me.

15 Q. Page 22, the last paragraph of section C.

16 A. Okay.

17 Q. It says, "It is my opinion to a reasonable
18 degree of medical certainty that the effect of chemical
19 and biologic degradation of the Bard mesh in a woman's
20 tissue can and does most often likely lead to the
21 greater foreign-body reaction and excessive scarring
22 complications."

23 Is that what it says?

24 A. That's what it says.

25 Q. Upon what do you base that the degradation that

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1 we've been discussing the last several minutes has any
2 clinical impact on the patient?

3 A. Because of the scarring that occurs in these
4 women after the product is removed.

5 Q. How do you know it's because of degradation?

6 MR. POTTS: Do not interrupt the witness.

7 Q. (BY MR. BORANIAN) I apologize.

8 A. Okay. Because I am the one who sits in the
9 operating room and takes it out, and I have seen what
10 kind of scarring occurs in this material.

11 And there is so much scarring that, in
12 fact, this product -- these products will come out as a
13 clump, as a fibrotic plate. And something that was put
14 in, even in the best of all circumstances, and allowed
15 to lie flat will, after having been in place for a long
16 time, instead come out like that, all wadded up.

17 It's solid scar. It's calcified. It's
18 extraordinarily difficult to take out. It is precarious
19 to take this stuff out because of its proximity to the
20 bladder on the top and to the rectum on the bottom if
21 we're dealing with a posterior vaginal wall implant.

22 If you're talking about the slings, it's
23 a challenge to get these thing out without getting into
24 the urethra. It's a challenge getting it out without
25 getting into the bladder.

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1 Q. In the Costello paper, the patient had a
2 hernia, correct?

3 A. Yes.

4 Q. And Dr. Costello did not attribute any of that
5 recurrence to degradation of the mesh, did he?

6 A. I think when there is a recurring hernia, I
7 think most experts would say that the problem is not
8 with the strength of the mesh per se.

9 In fact, in several of the articles that
10 I read, people talked about most mesh products as having
11 been, quote, over-engineered, and they created too good
12 a product.

13 The problem with recurrent hernia repair
14 has not to do with the center portion of the mesh but
15 the way the mesh was attached at the lateral aspects of
16 the hernia sac.

17 Q. Dr. Costello does not establish any clinical
18 experience to degradation of the mesh, does he?

19 A. I don't think he does.

20 Q. And Dr. Clave does not comment on any clinical
21 significance for degradation of the mesh.

22 So my question is -- and I appreciate
23 your testimony about scarring and scar plating.

24 But what is it -- how is degradation --
25 give me your basis for your opinion that degradation

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1 plays a part in any clinical injury to a woman.

2 A. Degradation in my opinion initiates the
3 inflammatory response. Something that was put in
4 initially and that was smooth and was allowed to lie
5 flat doesn't stay like that.

6 It begins to degrade through whatever
7 process, primarily through inflammation, and through the
8 attack of the micro fascias and the neutrophils that
9 immediately react to this foreign body. It's a classic
10 foreign-body reaction.

11 Q. Well, you're describing a foreign-body action.

12 A. Right.

13 And I think the degradation initiates
14 that.

15 Q. What is in your report, and what is in these
16 documents that supports that hypothesis, doctors?

17 MR. POTTS: Objection; overbroad,
18 previously answered.

19 A. That --

20 Q. (BY MR. BORANIAN) Foreign-body response
21 doesn't rely on degradation; does it, Doctor?

22 A. No. I can happen without a foreign body.

23 I mean, a foreign-body response has to
24 have a foreign body to happen, but degradation does not
25 depend on the presence of a foreign body, no.

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1 Q. But a foreign body such as polypropylene will
2 provoke a foreign-body response, right?

3 A. Of course.

4 Q. All I am trying to get at here is, what is the
5 basis of your opinion that degradation plays any role in
6 that process?

7 MR. POTTS: Objection.

8 A. I told you that degradation is the initiating
9 event.

10 And once there is a disturbance of that
11 surface membrane on the polypropylene, then the
12 inflammatory response begins, and the foreign-body
13 reaction accompanies that.

14 Q. (BY MR. BORANIAN) Can you cite any published
15 literature that cites that what you just said?

16 A. No.

17 That's common medical knowledge. I am
18 not out on a limb here. What I am telling you is
19 Inflammation 101.

20 Q. Well, I hear you on inflammation and I hear you
21 on foreign body, but I am not seeing a link to
22 degradation. That's all I am saying.

23 A. Okay.

24 Q. And you have not personally studied the
25 degradation of polypropylene mesh, have you?

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1 **A. How do you mean, studied it?**

2 **I have seen the clinical effects on it.**

3 Q. Have you done any animal studies regarding
4 testing the stability of polypropylene mesh?

5 **A. I have not.**

6 Q. Have you studied the stability of mesh?

7 **A. I have not.**

8 MR. POTTS: We've been going seven hours,
9 not including breaks.

10 What is your plan? 4:30?

11 MR. BORANIAN: 4:30 is fine.

12 Is that okay with you?

13 **THE WITNESS: Sure.**

14 MR. POTTS: It's been a long day. So...

15 Q. (BY MR. BORANIAN) Let's get started with the
16 next opinion, Doctor. It starts with page 23 of your
17 report. This is the section letter D.

18 And I will tell you, I will need your
19 help with this one, Doctor, because I have trouble
20 distinguishing opinion D from opinion E, okay?

21 **A. All right.**

22 Q. So let's talk through that.

23 So opinion D, Doctor, is, "Bard's Align
24 mesh is not suitable for its intended application as a
25 permanent prosthetic implant for SUI in the human body

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1 and is defectively designed and unreasonably designed
2 because of the chronic inflammatory response/foreign
3 body reaction resulting it creates resulting in fibrotic
4 bridging, scar plate formation, and mesh encapsulation."

5 Is that what you wrote, Doctor?

6 **A. That is my writing.**

7 Q. Is that your opinion?

8 **A. It is.**

9 Q. Now, we have agreed on the -- some of the basic
10 properties of the Align mesh, 1.3 millimeter pore size.

11 **A. Correct.**

12 Q. And the fibro diameter of about .3 millimeters,
13 right?

14 **A. Right.**

15 Q. So describe to me, Doctor, exactly what opinion
16 you have. Just describe it to me.

17 **A. The mesh, once implanted, initiates a**
18 **foreign-body response. The initial mesh products had**
19 **relatively small pore size, and they were relatively**
20 **brittle and relatively inflexible.**

21 **And as a result of placing that into the**
22 **body, the inflammatory response in the best of all**
23 **possible worlds would have allowed fibroblasts and blood**
24 **vessels and later nerve tissue to enervate this and to**
25 **put -- and for the mesh to serve essentially as**

1 scaffolding, which the body would then reinforce with
2 native tissue.

3 In the instance of many products,
4 including Align, this did not happen according to what I
5 have read due to pore size and due to the fact that
6 there was not enough room for fibroblasts and fibrous
7 tissue and blood vessels and nerves to get back into
8 this tissue.

9 And instead of being able to go into
10 relatively large pores, the foreign-body reaction, the
11 scar-plate formation was such that the calcifications
12 that would occur in scar tissue would overlies the entire
13 nerve implant, and there was no flexibility.

14 This became very rigid. It became very
15 hard. And in the human body, what was put in and
16 designed to be flat, became a clump of tissue.

17 And in my clinical experience, women who
18 have products inserted by surgeons who I knew, knew what
19 they were doing -- they were not sloppy -- they were
20 doing it the way it should have been done -- when the
21 patients would come in to see me, what was a flat piece
22 of tissue could in many instances become the size of a
23 large marble, or even a golf ball that was exclusively
24 tender to the touch.

25 Q. Have you ever seen an Align mesh form a golf

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1 ball?

2 **A. I have never seen an Align mesh become the size**
3 **of a golf ball.**

4 Q. You kind of lumped the Align mesh in there with
5 other small-pore meshes.

6 Is that right, Doctor?

7 **A. I did.**

8 Q. Now, take a look at opinion E on the next page.

9 **A. Yeah.**

10 Q. And there it says -- I am not going to read the
11 whole thing, but it says the Align mesh is not suitable
12 because of its failure to incorporate into the tissues
13 as a result of small, irregular pore sizes, weight, and
14 lack of elasticity.

15 And there, you talk first about pore size
16 and then talk next about shrink and contracture?

17 **A. Right.**

18 Q. And then next -- I think that's it.

19 **A. Okay.**

20 Q. So my question first is, is opinion D different
21 from opinion E?

22 **A. Well, I am talking about part of the same**
23 **thing.**

24 I am talking more specifically in E about
25 the pore sizes, the weight of the mesh, and the fact

1 **that it's not very flexible.**

2 Q. And you cover shrinkage and contracture as part
3 of the opinion E, correct?

4 A. Correct.

5 I think, too, though -- I don't know if
6 you're going to get to it. Since I opened my mouth, I
7 am going to finish it.

8 I think of all the things that we learned
9 about mesh that we didn't know, and we just started
10 putting it in, is the amount of shrinkage that occurred
11 with this product. That was something that was a
12 complete surprise to a lot of surgeons.

13 Q. Let's talk about that in just a minute.

14 Let's look at the -- the sources you cite
15 on page 23 of Exhibit D.

16 A. Okay.

17 Q. And the first one is --

18 A. Klinge.

19 Q. -- Klinge 1998.

20 And that is shrinking of polypropylene
21 mesh and the study of dogs, right?

22 A. Right.

23 Q. So do you want to --

24 MR. POTTS: "Klinge."

25 MR. BORANIAN: Thank you.

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1 Q. (BY MR. BORANIAN) So the Dr. Klinge is
2 studying shrinkage in dogs, right?

3 A. Right.

4 Q. So maybe we can discuss this one later.

5 But the first question is, what does this
6 article have to do with the scar-plate formation that
7 you're describing in -- in opinion D? It seemed like it
8 didn't quite fit.

9 A. Let me find the article. I have got more than
10 one Klinge.

11 Okay. The first one is abdominal wall.
12 And then the next Klinge article that I have is the
13 lightweight and large-porous concept for hernia repair.

14 Q. The one that I am asking about is the dog
15 study. That's the one cited on note 10 on page 23 of
16 your report.

17 Do you have a copy of that article?

18 A. Sure.

19 Q. That's not in your binder?

20 A. It's not in my binder, no.

21 I have a Klosterhalfen, "Lightweight and
22 Large Pore Concept for Hernia Repair."

23 And I have, "Modified Mesh For Hernia
24 Repair that is Adapted to the Physiology of the
25 Abdominal Wall."

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1 Q. So this is Klinge 1998.

2 (Reeves Exhibit No. 34 was marked.)

3 Q. (BY MR. BORANIAN) It is Exhibit 34. This is
4 the article that you cite in footnote 10. You also cite
5 it later on in footnote 11.

6 We can discuss it in connection with
7 shrinkage, which the paper clearly addresses, but my
8 question for now is, what does it have to do with the
9 scar-plating opinions that you are proffering, because I
10 don't see any connection whatsoever?

11 A. Okay. They don't specifically -- let's see.

12 On page 968, the second paragraph, the
13 top of the page, "After six months, the pore width of
14 the multifilament mesh has markedly decreased from
15 initially 2.54 plus/minus 0.46 millimeters to 1.85
16 plus/minus 0.28 millimeters. This corresponded to a
17 reduced length of 27 percent and a reduced area of 47
18 percent. The pore size of the mesh within reduced --
19 the pore size mesh with reduced amount of polypropylene
20 decreased from 4.99 plus/minus 0.56 millimeters to 4.15
21 plus/minus 0.41 millimeters, probability less than 0.01,
22 corresponding to a shortening of 16 percent and a
23 shrinking of the mesh area of 28 percent."

24 Q. So it addresses shrinkage, right?

25 A. Yes.

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1 Q. So maybe the best thing to do is set this aside
2 and discuss this when we get to mesh shrinkage.

3 A. But wasn't that your question, you wanted to
4 know what it had to do with shrinkage?

5 Q. Scar plating.

6 A. Oh, scar plating. I am sorry. I thought you
7 asked about shrinkage.

8 Q. Let's set Klinge aside for a moment.

9 A. Okay.

10 Q. Let's talk about Klinge 1999.

11 That one is on your list, right? Maybe
12 it isn't.

13 A. I have got European Journal of Surgery '98 in
14 here, and I have also got Klosterhalfen
15 WWW.futuredrugs.com.

16 (Reeves Exhibit No. 35 was marked.)

17 Q. (BY MR. BORANIAN) So this is Exhibit 35,
18 Doctor, and this is the Klinge 1998 study that you --
19 the 1999 -- let me check that -- yeah -- that you cited
20 in footnote 10 in your report.

21 A. Okay.

22 Q. Did you prepare these footnotes, Doctor?

23 A. Did I prepare?

24 Q. These citations for the footnotes.

25 A. No, I did not come up with the citations.

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1 MR. POTTS: Yeah.

2 Q. (BY MR. BORANIAN) I believe it's also referred
3 to as the Klosterhalfen article, which is No. 36 on your
4 list?

5 THE WITNESS: Yeah.

6 MR. POTTS: It's Klinge and
7 Klosterhalfen.

8 THE WITNESS: The one that I called --
9 let's see.

10 Q. (BY MR. BORANIAN) Well, the No. 36 is
11 Klosterhalfen and that's cited next.

12 A. Okay. The one that I called Klinge in my list,
13 he's actually the third author in that one.

14 The lead author is Vern Klosterhalfen.

15 Q. Okay.

16 A. That should clear that up.

17 Q. Well, let's just go back to the report and talk
18 about what you cited here.

19 A. Okay.

20 Q. We mentioned the dog study. We're going to
21 talk about that in a few minutes or maybe tomorrow.

22 The second study that you cite in your
23 report, Exhibit 10, in connection with the scar plating
24 opinion is Klinge 1999, "Foreign Body Reaction to Meshes
25 Used for the Repair of Abdominal Wall Hernias."

1 That's what I marked as Exhibit 35.

2 **A. Yes.**

3 **And you have handed me that.**

4 Q. So this is another study of mesh explants,
5 right?

6 **A. Right.**

7 Q. He's listed the explants in Table No. 1, hasn't
8 he?

9 **A. Yes, 18.**

10 Q. Yeah.

11 There are no Align meshes listed here,
12 are there?

13 **A. There are not.**

14 Q. And there are no Avaulta meshes listed here,
15 either, are there?

16 **A. I don't see any.**

17 Q. In fact, these are all hernia products, aren't
18 they?

19 **A. Correct.**

20 Q. Okay. So a total of 18 samples of implanted
21 mesh were removed during revision operations, right?

22 **A. Right.**

23 Q. So on page 668, he reports his findings as to
24 polypropylene, which includes seven Marlex, two Prolene,
25 and 1 Atrium mesh, right?

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1 **A. Right.**

2 Q. He doesn't describe the properties of any of
3 these meshes, does he?

4 **A. No.**

5 Q. He doesn't give, for example, the pore size or
6 the fiber diameter, correct?

7 **A. I don't see that.**

8 Q. He also discusses a product -- another
9 polypropylene product on page 669, and that's the Vypro
10 reduced polypropylene combined with --

11 **A. Which he calls Vypro.**

12 Q. I am sorry.

13 What?

14 **A. Which he calls Vypro.**

15 Q. Right.

16 And he's not given us any properties of
17 the Vypro mesh, either, has he?

18 **A. Not to begin with.**

19 He talks about the pore size of this mesh
20 having decreased considerably, but he doesn't talk --
21 and he does indicate pore size in the next-to-the-last
22 paragraph on page -- on page 669.

23 Q. So in the discussion, he says that all of the
24 samples showed some inflammatory response, right?

25 **A. Can you show me where you're reading**

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1 **specifically?**

2 Q. It shows in the last paragraph of the page,
3 "Experimentally, all meshes cause an initial and chronic
4 inflammatory tissue response in the recipient after
5 implantation."

6 It says that, right?

7 **A. It says that, yes.**

8 Q. And he saw some evidence of inflammation in all
9 of the samples, right?

10 **A. Right.**

11 Q. And you would expect to see that in a foreign
12 body implanted in the abdomen in this case, right?

13 **A. Yes.**

14 Q. In fact, that's how meshes purport to work, the
15 mesh provokes a foreign-body response providing anatomic
16 strength, correct?

17 **A. Correct.**

18 Q. So you would expect to see a foreign-body
19 response in any implanted mesh, right?

20 **A. Right.**

21 Q. And so to certain extent, that's an intended
22 desire and effect of the mesh, right?

23 **A. To an extent.**

24 **The question becomes how thick does the**
25 **fibrotic plate become and how brittle is the mesh**

1 **several months after implantation.**

2 Q. And there's several variables that can affect
3 the process, correct?

4 A. **Right.**

5 Q. There are patient variables, right?

6 A. **Right.**

7 Q. And variables with the quality of the mesh,
8 right?

9 A. **Right.**

10 Q. In fact, Dr. Kline says here in the next
11 sentence, "The quantity and quality of the local
12 inflammation depends directly on the mesh concern."

13 A. **Yes.**

14 Q. But the doctor hasn't given us the benefit in
15 describing any details the property of the implanted
16 mesh, has he?

17 A. **He has not.**

18 He has got some photomicrographs showing
19 what this looks like after implantation, but he doesn't
20 give any other information.

21 Q. So there's no way really to know how the
22 macroporous monofilament Align mesh really compares to
23 any of these explants, is there?

24 A. **I am not sure I understand what you're getting**
25 **to with that question.**

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1 **Can you repeat that in some other form?**

2 Q. Sure.

3 Dr. Klinge has reported inflammatory
4 response to -- that he's observed in hernia meshes,
5 right?

6 A. Yeah.

7 What you're saying, these are not Align
8 patients, and I am agreeing with that.

9 Q. Right.

10 A. And it's difficult to extrapolate from these
11 patients to Align patients, right.

12 Is that your question?

13 Q. Yes, that's my question.

14 A. Yes.

15 Q. I would say it's impossible to extrapolate,
16 isn't that right, Doctor, without knowing the properties
17 of the meshes involved?

18 A. I think it's comparing apples to oranges.

19 Q. Now, Dr. Klinge has recommended further study
20 as a result of this, correct?

21 A. Correct.

22 Counselor, that's the last sentence in
23 every paper you will ever read: "We recommend further
24 study."

25 Q. You do tend to see that a lot, don't you,

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1 Doctor?

2 A. You do.

3 Q. In fact, you probably wrote that in your
4 report, didn't you?

5 A. I may have.

6 Q. Well, going on, these explants were not
7 measured in the body, were they?

8 A. No.

9 Q. The measurements were taken all after they were
10 explanted, correct?

11 A. Correct.

12 Q. So can the explantation process and
13 environmental factors post-explant affect the properties
14 of explanted mesh?

15 A. It depends on how quickly the materials get to
16 the laboratory and how quickly Pathology looks at it.

17 I am not trying to be cutesy with you. I
18 am saying, I don't know how much change there's going to
19 be.

20 If something sits in a-- in a cardboard
21 box for three days before Pathology looks at it, it's
22 certainly going to have potential for drying. As a
23 result of drying, it's going to shrink some, because
24 it's simply not as big as it was because of the loss of
25 moisture.

1 In most instances, in good hospital
2 laboratories, when a piece of tissue was taken out, it
3 goes to the laboratory that day, and technicians will
4 begin the fixation process that evening.

5 Q. Well, one would hope, right, Doctor?

6 A. One would hope.

7 Q. Does Dr. Klinge report how the explants were
8 maintained in this case?

9 A. No, he does not.

10 Q. And sometimes you have to cut the mesh to get
11 it out, too, right?

12 A. Absolutely.

13 Q. So the explantation process can likewise result
14 in a change to the size and property of the mesh, right?

15 A. It's as big as it's going to be.

16 I think it depends -- the other issue is
17 how difficult is it to get out and how many pieces are
18 you going to have to take it out in. It's not likely
19 that you're going to be able to get it all out at one
20 time.

21 And in many instance, this is a very
22 slow, tedious, laborious process, getting the mesh out.

23 Q. So that's just another variable that could
24 affect the condition of the mesh once it's explanted,
25 right?

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1 **A. Right.**

2 Q. So take a look next at Dr. Klosterhalfen's
3 article that you have cited also in footnote 10. This
4 is Klosterhalfen 2005. That's it right there, Doctor.

5 (Reeves Exhibit No. 36 was marked.)

6 Q. (BY MR. BORANIAN) And we'll mark it as
7 Exhibit 36.

8 So let's look at what Dr. Klosterhalfen
9 says on page 104. And for the record, Exhibit 36 is
10 Klosterhalfen 2005, "The Lightweight and Large Porous
11 Mesh Concept for Hernia Repair."

12 This is a hernia article, right, Doctor?

13 **A. Yeah.**

14 **He's talking about -- the big issue here**
15 **is lightweight and large porous mesh concept, but he's**
16 **talking about hernia repair.**

17 Q. Okay. So on page 104, he's describing that
18 concept. He says on the first full paragraph of 104,
19 "As a consequence, today, two major mesh concepts are
20 distinguished. The classic concept, including so-called
21 heavyweight meshes with small pores, and the new
22 concept, including lightweight mesh in large pores."

23 That's the purpose of the article, right?

24 **A. Right.**

25 **I have got that outlined in red ink.**

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1 Q. And he goes on to say, "Typically the new mesh
2 generation is characterized by a reduced weight
3 depending on the specific weight of the basic polymer, a
4 pore size of more than 1 millimeter, an elasticity of 20
5 to 35 percent, and a physiologic tensile strength of 16
6 percent centimeters at minimum."

7 So according to Dr. Klosterhalfen, a mesh
8 with a pore size of more than 1 millimeter along with
9 other factors qualifies as the new-generation reduced
10 mesh, right?

11 **A. In his definition, that is correct.**

12 Q. So when he's comparing lightweight mesh to
13 heavyweight mesh, according to his criteria, the Align
14 mesh would fit into the lightweight mesh category?

15 **A. According to his criteria.**

16 Q. Okay. So in the end,
17 Dr. Klosterhalfen observes -- well, first let's go over
18 this concept. On page 109, the last sentence of 109 --
19 the last two sentences, actually, he says, "Furthermore,
20 the data pool of the retrievable study demonstrates a
21 reaction of different hosts the different in. The
22 individual reaction of the patient on to an implant
23 plant depends on the genetic background of each host."

24 That's what he said?

25 **A. I had that outlined in red ink, too.**

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1 Q. So an individual's reaction to the mesh is a
2 major variable in how that mesh performed, correct?

3 A. That is correct.

4 Q. So I don't think we established yet, this is --
5 what is Dr. Klosterhalfen doing here?

6 He's comparing explanted meshes, correct?

7 A. He is talking about -- you know, I think this
8 is not a clinical article, in the sense that he's
9 talking about X numbers of patients. This is not a
10 clinical study. This is a concept study, if I can use
11 that phraseology.

12 There are some photo micrographs of
13 histology here, but this is not talking about a specific
14 number of patients in whom explants were taken out of
15 these patients. There's no listing of any patients.

16 Q. So to the extent he's presenting data, he's
17 relying on measurements of explanted meshes, right?

18 Look at table 3 and 4, for example. He's
19 giving us the results of post-retrieval study involving
20 347 explanted meshes.

21 A. Excuse me.

22 What page are you on with that?

23 Q. Tables 3 and 4 on page 109.

24 A. Okay.

25 Q. To the extent he's presenting data, it's data

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1 based on explanted meshes, right?

2 **A. Yes.**

3 Q. And these are hernia meshes, right?

4 **A. Correct.**

5 Q. And again, we don't know if the Align is
6 similar to or the same as these products?

7 In fact, we know Align to be a low-weight
8 mesh by his criteria, right?

9 **A. Right, by his criteria.**

10 Q. So let's look at where he's talking about
11 shrinkage of the hydraulic bridges on page 111.

12 He says, "At the beginning, the concept
13 of shrinkage of the mesh was enthusiastically debated."

14 You would agree with that, right, Doctor?

15 **A. Yes, I do.**

16 Q. It is not the mesh that shrinks, but the
17 surface reduction is due to a simple retraction of the
18 fibrotic scar tissue around the mesh.

19 You agree with that, right, Doctor?

20 **A. Yea.**

21 That's probably splitting hairs, because
22 you're going to have to measure something when you take
23 it out. And when you take out -- when you explant mesh,
24 it is surrounded in most instances by fibrotic tissue.

25 And you -- what you're taking out is in

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1 most instances smaller than what was put in.

2 Q. And that's because of the tissue and growth?

3 A. Yes.

4 And I don't think it's ever going to be
5 possible to separate the tissue from the mesh to answer
6 your question specifically, but I agree with you that
7 most of the shrinkage that we're talking about here,
8 when we're talking about the shrinkage of the mesh, is
9 due to the scar plate that forms around it.

10 Q. Have you -- have doctors tried to wash away the
11 human tissue to get down to the mesh?

12 Has that study been done?

13 A. Not that I -- you need to be in the operating
14 room to appreciate what we have to do.

15 It's like chiseling concrete to get this
16 stuff out of many patients, and it's very difficult to
17 measure the length or the width of what you take out
18 because you're talking about something that was
19 2-dimensional becoming 3-dimensional. And it's not a
20 flat piece of mesh any longer. It's a chunk of mesh
21 with tissue imbedded in it.

22 And I don't think anybody makes an
23 attempt to pull the mesh away from the tissue.

24 Q. Have you seen that in an Align mesh, Doctor?

25 A. Yeah, I have.

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1 Q. Now, in terms of fibrotic bridging, which is
2 what Dr. Klosterhalfen discusses next, he says,
3 "Fibrotic bridging is a phenomenon which is, in the
4 authors' opinion, closely associated with the occurrence
5 of shrinkage."

6 You agree with that, right, Doctor?

7 **A. Agreed, yes, absolutely.**

8 Q. And it says here, "Moreover, the incidence of
9 bridging is unrelated to the textile structure of the
10 mesh. Bridging occurs in all mesh modifications with a
11 granuloma size around each mesh fiber exceeding more
12 than half the pore size of the mesh."

13 Is that what it says, Doctor?

14 **A. That's what it says.**

15 Q. Now, Doctor, the Align mesh at .1 millimeters,
16 that's large enough to be twice the size of a granuloma,
17 isn't it?

18 **A. It is.**

19 Q. And he goes on to say, "Usually the phenomenon
20 of bridging is observed in all mesh modifications with
21 pore size of less than 1 millimeter."

22 Is that what he says, Doctor?

23 **A. That's what he says.**

24 Q. And the Align mesh at the center is greater
25 than 1 millimeter?

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1 **A. At the center.**

2 Q. And at the arms, it's 1.3 even, correct?

3 **A. I think that's correct.**

4 Q. So again, by Dr. Klosterhalfen's own analysis,
5 the Align mesh is the type of mesh in which you wouldn't
6 expect to see the phenomenon of bridging, correct?

7 **A. Yeah.**

8 But what you expect to see based on this
9 versus what I have seen when we take out the Align
10 product is not necessarily one and the same.

11 And I don't think -- you know, you can
12 theorize about this until the cows come home, and it's
13 not going to make any difference.

14 Q. Well, he's not theorizing.

15 He's looking at implanted mesh just the
16 same as you are, right?

17 **A. But he doesn't have a single Align product in**
18 **front of him. We've both established that.**

19 Q. Your observations are of patients that have had
20 problems with the Align product?

21 **A. Correct.**

22 Q. And we agree that the post-reaction to the
23 product is a major variable in the instance of fibrosis
24 and contraction, correct?

25 **A. Agreed.**

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1 Q. So you haven't seen the much, much larger
2 majority of patients whom experienced no complications,
3 right?

4 A. If they haven't had a complication, I haven't
5 seen them.

6 Q. So you're basing your experience on your
7 anecdotal observation of 10 to 15 Align meshes?

8 A. Correct.

9 But remember, for those people, it was
10 100 percent.

11 Q. There I agree with you 100 percent.

12 Low complications are critically
13 important, but it doesn't matter much to that one
14 person, does it?

15 A. Right.

16 Q. That's not issue for the generic opinions.

17 If you look at what Doctor
18 Dr. Klosterhalfen says further down on fibrotic
19 bridging, it says, "Fibrotic bridging is mostly found in
20 heavyweight small-pore-size meshes," which does not
21 include the Align mesh, right?

22 A. Right.

23 Q. Lower down he says, "In contrast, lightweight
24 meshes with large pores are constructed in such a way
25 that the granuloma is always notably smaller than half

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1 of the pore size."

2 That does include the Align mesh?

3 **A. Right.**

4 Q. You rely on Dr. Klosterhalfen to form your
5 opinions, right?

6 **A. This is one of 100 articles that I have read.**

7 I pay credence to what he's written here.
8 I am not telling you that everything he says, I would
9 100 percent agree with. But I think it's a superb paper
10 and I relied on it and I think it's interesting.

11 Q. Have you talked to him?

12 **A. No.**

13 Q. So Dr. Klosterhalfen says later on, when he's
14 discussing polypropylene in particular -- and that
15 starts on page 112.

16 He says here at the beginning, "Most
17 manufacturers have added to their range of PP
18 heavyweight small porous mesh modifications, a
19 lightweight large porous adaptation. There are also
20 numerous monofilament PP meshes on the market, which
21 fulfill all of the criteria for a flexible lightweight
22 mesh with reduced material."

23 That includes C.R. Bard, right?

24 **A. Where are you reading from?**

25 Q. Polypropylene on page 112.

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1 **A. Okay.**

2 Q. And that includes C.R. Bard, right?

3 Bard has a lightweight product, the Align
4 product, right?

5 **A. Yes.**

6 Q. And then at the last paragraph of the
7 polypropylene section, it says, "Biocompatibility of the
8 new generation of lightweight PP meshes in experimental
9 studies is acceptable when a significantly decreased" --

10 **A. Foreign-body reaction.**

11 Q. "And only a minor fibrotic reaction around the
12 PP mesh fibers after long-term implantation in rats.
13 However, clinical trials have yet to confirm the
14 promising preclinical results."

15 You agree with that, right, Doctor?

16 **A. Sure.**

17 **What he's saying is it's a good idea. We**
18 **don't have any data yet.**

19 Q. It shows acceptable biocompatibility with a
20 significant decreased foreign-body reaction and minor
21 foreign-body reaction in rat studies, right?

22 **A. Yeah, I agree, in rat studies.**

23 Q. And that's where you would start, right?

24 **A. I would start with animal studies, yes.**

25 Q. You cited a study by Dr. Binnebosel. This is,

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1 "The Biocompatibility of Prosthetic Meshes," and we'll
2 mark it as Exhibit 37.

3 (Reeves Exhibit No. 37 was marked.)

4 Q. (BY MR. BORANIAN) And I have said already the
5 title of the Marcel Binnebosel, B-i-n-n-e-b-o-s-e-l.
6 This is 2011.

7 First of all, this is a literature
8 review, right, Doctor?

9 A. Yes.

10 Q. So he's not actually studying or doing a study
11 of mesh, right?

12 A. Correct.

13 Q. He does, however, say based on his review, if
14 you look at pore size --

15 A. Our page, please, sir?

16 Q. Page 237.

17 A. Yes.

18 Q. His -- his last word there is,
19 "Correspondingly, only pores with a diameter of greater
20 than 1 millimeter are regarded as appropriate."

21 A. That's what he says.

22 Q. And that would include the Align mesh, right?

23 A. Right.

24 Q. Now, we're not going to go for much longer,
25 Doctor, at Mr. Potts' request. Let's talk for a minute

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1 about opinion E on page 24.

2 **A. Okay.**

3 Q. Let me ask you first, Doctor, the -- before we
4 get to that, the studies that you have cited in support
5 of your opinion D on scar plating and fibrotic bridging,
6 those all talk about fibrotic bridging in meshes with a
7 pore size less than one millimeter, right?

8 **A. Right.**

9 Q. So what support do you cite, Doctor, in support
10 of your opinion that a mesh like the Align mesh with the
11 pore size ranging from 1 millimeter to 1.3 millimeters
12 has an unacceptable level of fibrotic bridging?

13 **A. Align -- excuse me -- Bard talked about the**
14 **fact that they would like to have the mesh with larger**
15 **pore size, and that was mentioned in their depositions.**

16 Q. Well, we'll get into that proposal, I guess,
17 first thing in the morning.

18 But what support do you have for your
19 opinion that the mesh as it's currently constructed --
20 not as it's proposed to be constructed, as it's
21 currently constructed has an unacceptable level of
22 scar-plate formation and fibrotic bridging based on the
23 articles that we've seen that you chose to cite in the
24 report talk about bridging and scar plating in mesh of
25 smaller pore size?

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1 MR. POTTS: Objection; asked and
2 answered.

3 He's allowed to talk about whatever he
4 wants that supports his opinions. He just tried to tell
5 you.

6 A. Bard was -- I got the impression from their
7 depositions that they were not pleased with the size of
8 the pore size in the Align product, and they wanted
9 larger pore size.

10 I am also telling you that a lot of this
11 is on the basis of my clinical experience. When I sit
12 down and take this stuff out, I don't have any idea what
13 the pore size was. I see the end result of the product.

14 And I am not telling you that it's
15 strictly a pore-size phenomenon that has caused the pain
16 and suffering that these women have had. I think pore
17 size is important.

18 I think if I were designing the perfect
19 mesh, it would be very thin, the fibers wouldn't be
20 large, and the pore size could be huge.

21 But I think what we have to deal with is
22 the fact that there are some significantly-injured
23 patients here, and they don't care one way or the other
24 what the pore size is. They want relief for their pain
25 and suffering.

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1 Q. There are risks and benefits involved in every
2 surgical procedure, right?

3 A. Absolutely.

4 Q. And even if you have the perfect medical device
5 that meets every criteria of every kind, there's going
6 to be a risk involved in implanting that device, right?

7 A. Right.

8 Q. Because there are patient factors, right?

9 A. There can be, yes.

10 Q. And there are factors involving the surgical
11 technique, right?

12 A. Right.

13 Q. And there are factors involved in the
14 implantation of devices that create risks that you can't
15 designed out of the device, right?

16 A. I don't know that I would agree with that
17 necessarily.

18 Q. Synthetic mesh, it's going to provoke a
19 foreign-body reaction?

20 A. It is.

21 Q. You can't design that out of the mesh, can you?

22 MR. POTTS: Objection; argumentative.

23 A. I don't know if you can or not.

24 Certainly the mesh manufacturers have
25 done -- they are continuing to improve these products.

1 You know, if -- if Ford had made the
2 perfect car in 1920, they would have never made a new
3 model.

4 Q. (BY MR. BORANIAN) And you would expect Bard
5 and others to keep improving their products, right?

6 A. I would hope so.

7 Q. So getting back to the original question, so
8 the basis of your opinions on fibrotic bridging and scar
9 plating is based on your observations of complication of
10 the patients, right?

11 A. Right.

12 Q. And also your review of Bard documents, right?

13 A. Yes.

14 MR. BORANIAN: Okay. Do you want to
15 break there for the day?

16 THE VIDEOGRAPHER: We are off the record.
17 The time is 4:36 p.m.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC., PELVIS MDL NO. 2817
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL
CASES IN MDL NO. 2187 AND
SPECIFICALLY TO:

PAMELA DOUGLAS-JONES
AND TOMMY JONES,

Plaintiffs, CIVIL ACTION NO.
2:13:cv:17990

v.

C.R. BARD, INC.,
Defendant.

KRISTIA GROOVER AND EARL
GROOVER,

Plaintiffs CIVIL ACTION NO.
2:12:cv:00173

v.

C.R. BARD, INC.,
Defendant.

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1
2 PAMELA RAE GRUMAN AND

3 LARRY FRANK GRUMAN,

4 Plaintiffs

CIVIL ACTION NO.

5 2:13:cv:02168

6 v.

7 C.R. BARD, INC.,

8 Defendant.

9 ALMA D. MESSER,

10
11 Plaintiffs

CIVIL ACTION NO.

12 2:12:cv:06600

13 v.

14 C.R. BARD, INC.,

15 Defendant.

16 DEBRA A. MITCHELL AND

17 JERRY MITCHELL,

18 Plaintiffs

CIVIL ACTION NO.

19 2:12:cv:05532

20 v.

21 C.R. BARD, INC.,

22 Defendant.

23 DEBORAH VILLNAVE,

24 Plaintiffs

CIVIL ACTION NO.

25 2:11:cv:00837

v.

C.R. BARD, INC.,

In Re: C.R. Bard (200)

Keith Reeves, M.D.

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1 Defendant.

2 MYRA WHITE,

3 Plaintiffs

CIVIL ACTION NO.

4 2:13:cv:02038

5 v.

6 C.R. BARD, INC.,

7 Defendant.

8 REPORTER'S CERTIFICATION OF THE ORAL AND VIDEOTAPED

9 DEPOSITION OF KEITH O. REEVES, M.D.

10 NOVEMBER 3, 2014

11 I, Samantha Downing, Certified Shorthand Reporter
12 in and for the State of Texas, hereby certify to the
13 following:

14 That the witness, KEITH O. REEVES, M.D., was duly
15 sworn by the officer and that the transcript of the oral
16 deposition is a true record of the testimony given by
17 the witness;

18 I further certify that pursuant to the FRCP RULE
19 30(f)(1) that the signature of the deponent:

20 X was requested by the deponent or a party
21 before the completion of the deposition and that
22 signature is to be before any notary public and returned
23 within 30 days of receipt of the transcript. If
24 returned, the attached Changes and Signature Page
25 contains any changes and the reasons therefore:

In Re: C.R. Bard (200)

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11/03/2014

was not requested by the deponent or a party before the completion of the deposition.

I further certify that I am neither counsel for, related to, nor employed by any of the parties or attorneys in the action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of the action.

Certified to by me this 5th day of
November, 2014.

Samantha Downing

SAMANTHA DOWNING, CSR, CLR

Certified Shorthand Reporter

in and for the State of Texas

Certificate No. 7512

Expiration date: 12-31-2014